S. HRG. 98-350

TASK FORCE REPORT ON PERTUSSIS

HEARING

BEFORE THE

COMMITTEE ON LABOR AND HUMAN RESOURCES UNITED STATES SENATE

NINETY-EIGHTH CONGRESS

FIRST SESSION

ON

EXAMINATION OF THE TASK FORCE REPORT ON THE VACCINE PERTUSSIS

JULY 22, 1983

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TASK FORCE REPORT ON PERTUSSIS

FRIDAY, JULY 22, 1983

U.S. SENATE,
COMMITTEE ON LABOR AND HUMAN RESOURCES,
Washington, D.C.

The committee met, pursuant to notice, at 9:29 a.m., in room SD-430, Dirksen Senate Office Building, Senator Paula Hawkins (acting chairman of the committee) presiding.

Present: Senator Hawkins.

OPENING STATEMENT OF SENATOR HAWKINS

Senator HAWKINS. Good morning. The hearing will come to order.

Today's subject is childhood immunization. Immunization is one of society's most valuable weapons for combating communicable disease. This country's childhood immunization program has contributed enormously to the suppression and virtual eradication of some once dreaded diseases. Unfortunately, immunizations are not without potential hazards, however. All vaccines, including those properly manufactured and administered, are capable of producing adverse reactions. While most of the adverse reactions are mild and self-limiting, a certain number of vaccinees do experience severe reactions that result in permanent disabilities and sometimes death. Solid statistics to quantify the incidence of serious adverse reactions are unavailable, and though they may occur only rarely, the cost to the injured vaccinees and to his or her family is extremely high.

At this juncture, I most emphatically repeat what I have stated all along. Parents should not be frightened to have their children immunized. It would be tragic if efforts to eliminate or control communicable disease become hampered because the public's confidence was so eroded as to cause segments of the population to reject vaccines. We cannot afford revival of serious epidemics, a result which would most surely follow public opposition to vaccines. We cannot forget the iron lung. To prevent pain and suffering, we must vigorously guard against inadequate immunization of our children.

At hearings I chaired in May of 1982, I learned that the current pertussis vaccines in use in the United States were accompanied by unwanted side effects ranging from minor transient reactions to much more disturbing reactions. The occurrence of occasional central nervous system reactions to pertussis vaccines is well-established, ranging from simple, short-lived convulsions to encephalopathy with permanent brain damage and, rarely, death.

From testimony presented at the hearing, I drew several conclusions.

First, to combat the fear of adverse reactions to vaccine administration and to maintain high immunization rates, full public communication and health education is essential. The general public really has a right to be given information about vaccines. The issues must be presented to the public clearly, with candid disclosure of the risks as well as the benefits of vaccines. If a vaccination is not recommended for particular classes of individuals, that fact should be stated and those high-risk individuals screened, if possible, to prevent administration of the vaccine to them. Parents should be fully informed and on the lookout for adverse reactions. Accurate and timely reporting and statistical gathering on adverse reactions is critical in order that a realistic picture of the problems associated with the use of a particular vaccine can be compiled. Risks from vaccines also warrant increased efforts to produce safer vaccines.

To reduce the risks to children of significant adverse reactions to pertussis vaccines and to restore confidence in the program, I requested that appropriate individuals within the U.S. Department of Health and Human Services conduct a study to review and summarize available information with regard to the safety and effectiveness of pertussis vaccines used in the United States and other countries.

Then Secretary of Health and Human Services, Richard S. Schweiker, willingly agreed to undertake such a study and appointed Dr. Edward N. Brandt, Jr., Assistant Secretary for Health, to have the interagency group to monitor vaccine development, production and usage, complete the study.

Today we will receive testimony from the representative of the interagency group on their findings and recommendations with regard to the pertussis vaccine. I want to take this opportunity to thank the members of the interagency group for their efforts, and I look forward to receiving their testimony.

Immunization programs serve a special, public function in our society. All 50 States have implemented legislation making immunizations mandatory for school admission. Because school attendance is also required by law, parents must have their children immunized or risk criminal prosecution for failure to send their children to school. And because vaccinations are mandatory for school entry, even a properly warned vaccine recipient cannot always be considered to have accepted all of the risks of injury—refusal is difficult, if not impossible.

Moreover, large-scale public participation in the immunization program is essential to its success. Each of us benefits from the individual's decision to be immunized. Where society has received a benefit of such magnitude, it is only fair that this benefit be matched by a public commitment to insure some form of compensation to those unavoidably injured, and the compensation should be fair and expeditious. Today we will examine the question of who should bear the risk for injuries resulting from critically important immunization programs.

There is another issue related to the immunization program that is of grave concern to me, and that is the threat to the security of

the vaccine supply in this country. The number of firms engaged in the manufacture of vaccines in the United States has declined dramatically in the past 15 years. A 1979 Government study verified that since 1968 the number of vaccine manufacturers with activities in the United States had decreased by one-half; the number of licensed vaccine products had declined by 60 percent over the same period; and there is only one pharmaceutical manufacturer in the entire United States for 19 types of vaccine products and no U.S. manufacturer of 11 other vaccine products.

One by one, U.S. vaccine manufacturers have decided that this business is not commercially attractive and have dropped out. Why? Rising costs and inadequate prices have been a significant factor in the decision to withdraw from the vaccine markets, but a major vulnerability is the unresolved public policy problem of liability for unavoidable injury in mass immunization programs. The specter of high and uncertain damage awards contributes to driving manufacturers out of vaccine production.

The president of a major vaccine manufacturing company in this country recently informed me that one reason price increases on vaccines are necessary is that the number of litigious suits can suddenly increase, as can awards granted to plaintiffs. In his company's case, 50 percent of all liability claim dollars were attributable to vaccines, which represent less than 10 percent of their entire business. Therefore, it is absolutely vital that we not lose the remaining domestic sources which supply the U.S. population with vaccines.

Increased vaccine costs also threaten the childhood immunization program in another way. Quite simply, dramatic increases in price mean that fewer children will be immunized. Because of this fact, I was concerned to learn from a spokesperson of one of the three private pharmaceutical companies currently manufacturing the pertussis vaccine that the cost of a 15-dose vial of pertussis vaccine increased from $4.67 to $42 in June of this year. That is a tremendously high increase. A company spokesperson told my staff that they had only two alternatives: either to discontinue manufacture of the vaccine or to radically increase its price. We see which choice they made.

In no way can we risk resurgence of serious childhood epidemics, nor can we turn our backs on the children who are injured as a result of vaccine administration. Public policy dictates that safe and effective immunization programs be implemented and maintained, and it is my sincere hope that the hearing today will promote these goals.

Our first panel of witnesses will be composed of the Public Health Service Interagency Group to Monitor Vaccine Development, Production and Usage. We will ask them to come forward. They are: Dr. Walter Dowdle, the Director of the Center for Infectious Diseases, Centers for Disease Control, who is also chairman of this group; Dr. William S. Jordan, Jr., the Director of the Microbiology and Infectious Disease Program, National Institute of Allergy and Infectious Diseases at the National Institutes of Health; Dr. John C. Petricciani, who is Director of the Office of Biologics, Food and Drug Administration; and Dr. Kenneth J. Bart, Chief of the Surveillance, Investigations, and Research Branch, Division of Im-

munization, Center for Prevention Services, Centers for Disease Control.

We welcome you all here today. That is quite a mouthful. Your titles are overwhelming.

I look forward to your statements. We have copies of your full statements, and we would ask that you condense them, summarize them, for this hearing, please.

Dr. Dowdle, we will call on your first.

STATEMENT OF WALTER R. DOWDLE, PH. D., DIRECTOR, CENTER FOR INFECTIOUS DISEASES, CENTERS FOR DISEASE CONTROL, ACCOMPANIED BY DR. WILLIAM S. JORDAN, JR., DIRECTOR, MICROBIOLOGY AND INFECTIOUS DISEASE PROGRAM, NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES, NATIONAL INSTITUTES OF HEALTH; DR. JOHN C. PETRICCIANI, DIRECTOR, OFFICE OF BIOLOGICS, FOOD AND DRUG ADMINISTRATION; AND DR. KENNETH J. BART, CHIEF, SURVEILLANCE, INVESTIGATIONS, AND RESEARCH BRANCH, DIVISION OF IMMUNIZATION, CENTER FOR PREVENTION SERVICES, CENTERS FOR DISEASE CONTROL

Dr. DOWDLE. Thank you, Madam Chairman.

Since we have submitted the full report and since we have submitted the formal testimony to you, we will attempt to summarize within a short period of time.

In the process of gathering information for this report, we met with representatives of the organization, Dissatisfied Parents Together, and private individuals at a public meeting held on April 26. We appreciate the concern of parents expressed at that meeting and information provided to us by others. A transcript of the open meeting and copies of subsequent submissions are included in the report.

Clearly we are all in complete agreement as to our ultimate goal, and that is to provide to our children the maximum protection from pertussis through the use of a vaccine which produces minimal adverse effects.

The preparation of this report provided us the opportunity to review the progress that has been made and the work yet to be done to achieve that goal.

Our comments on the seven items may be summarized as follows:

First, in reference to the diagnosis, reporting, and recordkeeping concerning the incidence and severity of pertussis and significant adverse reactions to pertussis vaccines:

The news reports of several weeks ago of a pertussis death in the Washington area serve as a reminder that whooping cough, or pertussis, is still very much with us. In this area alone, Maryland has reported 15 cases during the first 26 weeks of this year. For the same period, Virginia has reported 41 cases, with one death. Nationwide, CDC has received reports of 891 cases, for the same period of time.

The majority of cases of whooping cough are caused by *Bordetella pertussis*. This is the organism contained in the vaccine, but there are other organisms which may cause similar symptoms for which the vaccine may be ineffective. Precise laboratory tests are

required to define the full spectrum of illness caused by *B. pertussis* as well as to evaluate vaccine efficacy. Current diagnostic tests are technically difficult or have low reliability. Many reported cases are diagnosed solely on clinical grounds.

We could increase the number as well as the quality of laboratory-confirmed reports by providing more practical and reliable diagnostic tests. The Public Health Service is committed to the development of such tests. One test is being evaluated now, and the evaluation of a second will begin late this summer.

Pertussis is officially required to reported by agreement of all 50 States, but we believe that underreporting is substantial. Since the degree of underreporting is likely to be relatively constant, the data are felt to give an accurate indication of trends of disease incidence. A precise count of the pertussis cases cannot be easily achieved, but we have made recommendations that relate to developing standardized case definitions, modifying and increasing the use of individual case record forms, and increasing the number of disease and outbreak investigations that we feel will improve the quality and quantity of disease reporting.

Public Health Service efforts in each of these areas are presently underway.

In addition, report forms are being modified to enhance the quantity and quality of information about suspected adverse reactions following vaccination and to permit followup in the public sector.

However, a report of an adverse effect following vaccination does not necessarily mean that the event was caused by the vaccine. This is particularly true of seizures. Approximately 5 percent of all children will have a febrile or nonfebrile seizure before reaching their seventh birthday. Thus, the incidence rate of seizures is highest during the period that coincides with administration of pertussis vaccine.

Valid data on the frequency of adverse events following vaccination can be obtained only by carefully designed scientific studies which compare the frequency of such events in vaccinated and unvaccinated children. Such a study is presently being planned by CDC.

In regard to the need to insure full discussion about vaccine risk and benefits between parents and providers, we feel confident that efforts already underway in the public sector will prove to be effective. Information documents on pertussis disease and pertussis vaccines have been developed, one for the health care provider and the second for parents. The important information statement which each parent or guardian in the public sector must sign also has been expanded.

Insuring full discussion in the private sector is far more difficult. The FDA, however, plans to work through direct and indirect educational efforts with the American Academy of Pediatrics and other groups, and will explore possibilities of assuring maximum awareness on the part of physicians and parents as to vaccine risk and benefits.

The second item in the proposed bill dealt with the availability of techniques for the purification of or extraction from existing pertussis vaccines in order to reduce the reactogenicity of such vac-

cines without rendering such vaccines unable to meet applicable potency standards.

We made recommendations in the report that should assist in development of pertussis vaccines that have decreased potential for adverse reactions. Such efforts, which are presently underway, include laboratory research supported by the NIH, both extramural and intramural, and the Food and Drug Administration. Also, a National Institute of Allergy and Infectious Diseases contract, for the development of acellular pertussis vaccine is to be awarded in 1983.

A vaccine has been produced in Japan which contains only soluble antigenic material, but little information is available on the vaccine, and no large efficacy trials have been conducted.

To accelerate development of an acellular or potentially less reactive vaccine, the National Institute of Allergy and Infectious Diseases has offered four of their vaccine evaluation units for safety and antigenicity testing of any new pertussis vaccines by commercial manufacturers.

Other U.S. and foreign manufacturers are also working on versions of an acellular vaccine which should prove to have minimal side effects while provoking good antibody responses.

The third item addressed in the bill was the availability or development of procedures or techniques for identifying children, or categories of children, who may be susceptible to significant adverse reactions to pertussis vaccines.

The Advisory Committee on Immunization Practices and the American Academy of Pediatrics Committee on Infectious Diseases have identified contraindications to receiving pertussis vaccines. One major contraindication listed by both groups is the history of having had a severe reaction to a preceding dose of vaccine. In Britain contraindications include a history of epilepsy in a child or in the child's family or a history of reactions to pertussis vaccine in another family member.

In our report we recommend that the Public Health Service rediscuss with the Advisory Committee on Immunization Practices and the American Academy of Pediatrics regarding all contraindications to receiving the vaccine in hopes of excluding high-risk children.

Toward this end, CDC is undertaking an extensive review of the data in this and in other countries. The results of that review will be presented to the Advisory Committee on Immunization Practices at its next meeting this coming October and also will be made available to the Academy.

Item No. 4 in the proposed bill referred to the current public and private efforts to develop and demonstrate clinically a pertussis vaccine which is safer than the pertussis vaccines currently used in the United States. As we have already indicated, the National Institute of Allergy and Infectious Diseases has made available the mechanism for testing of the safety and antigenicity of new vaccines, including pertussis.

The Office of Biologics (FDA) will be participating, as indicated earlier, by testing a variety of laboratory and clinical specimens.

There are also three commercial manufacturers of pertussis vaccine in the United States, and each manufacturer has stated that

they have a program in place to improve currently marketed vaccine.

The introduction of the Japanese vaccine into the United States will depend upon settling the liability issues and demonstrating that the product meets the U.S. standards for potency and safety.

The National Institute of Allergy and Infectious Diseases and the FDA will assist U.S. manufacturers in testing the Japanese vaccine.

Item No. 5, in the proposed bill referred to the association, if any, between pertussis vaccination and sudden infant death syndrome and the need for further studies of such association:

The possibility that DTP vaccination might cause sudden infant death syndrome has been raised in several publications, however, most of which represented uncontrolled studies. Perhaps the most definitive study is the multicenter study funded by the NIH. Analysis of approximately one-half of the study data has been completed. This study in 1982 revealed a lower frequency of DTP vaccination in sudden infant death syndrome cases than in their living controls. A study in Britain also indicated that such cases were less likely to have been vaccinated than were their living controls.

A preliminary analysis of the entire study population with regard to the history of DTP vaccination will be available in the fall of this year. We do not recommend further studies until these data have been analyzed.

Item No. 6, in the proposed bill concerned the creation and operation of a Federal compensation program for individuals who are seriously injured as a result of adverse reaction to the pertussis vaccine:

Within the United States, there has been extensive consideration of issues relating to establishment of a compensation system. The American Academy of Pediatrics has drafted a specific proposal for compensation and vaccine-related damage. To date, the Department of Health and Human Services has not adopted a position regarding establishment of a compensation system but the Department is continuing to look at the issue.

The final item we were asked to address concerns administrative and legislative changes which are necessary to carry out the purposes of the act.

The two major challenges that we face in the prevention of pertussis are: first, to educate the medical community and the public as to the risks of pertussis disease and the benefits and risks of pertussis vaccine, and, second, to provide a pertussis vaccine which has minimal adverse effects. Both of these challenges can be met and progress continues to be made under our present administrative structure and under present legislative authority.

In summary, pertussis remains a serious public health threat. The United States is continuing to seek an increase in our immunization levels. The American Academy of Pediatrics' Committee on Infectious Diseases and the Public Health Service Advisory Committee on Immunization Practices continue to recommend pertussis vaccination. The lesson learned from Britain during the past few years is clear: the benefits of pertussis vaccination far outweigh the risks.

We in the Department and the Public Health Service accept the responsibility to continue to reduce those risks of vaccination. A full report of our progress will be provided to the Assistant Secretary for Health on November 15, 1983.

This concludes my formal statement, Madam Chairman. We will be glad to answer any questions.

[The prepared statement of Dr. Dowdle follows:]

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Centers for Disease Control
Atlanta, Georgia 30333

Statement of

Walter R. Dowdle, Ph.D.

Director, Center for Infectious Diseases

Centers for Disease Control

and

Chairman, Public Health Service Interagency Group

to Monitor Vaccine Development, Production and Usage

Before the

Committee on Labor and Human Resources

United States Senate

Washington, D.C.

July 22, 1983

Mr. Chairman and Members of the Committee, I am Dr. Walter R. Dowdle, Director of the Center for Infectious Diseases of the Centers for Disease Control. I am here before you today as Chairman of the Public Health Service Interagency Group to Monitor Vaccine Development, Production, and Usage. With me today are representatives of the three Public Health Service Agencies constituting the Interagency Group: Dr. William S. Jordan, Jr., Director, Microbiology and Infectious Diseases Program, National Institute of Allergy and Infectious Diseases, National Institutes of Health; Dr. John C. Petricciani, Director, Office of Biologics, Food and Drug Administration; and Dr. Kenneth J. Bart, Chief, Surveillance, Investigations, and Research Branch, Division of Immunization, Center for Prevention Services, Centers for Disease Control.

As you know, in September 1982, Senator Hawkins introduced S. 2950, "A bill to require a study on the safety and efficacy of pertussis vaccine." In response to a specific request from Senator Hawkins, then Secretary Schweiker agreed to develop the study administratively, expressing his firm support for the intent of the activities outlined in the proposed legislation. The Secretary asked the Assistant Secretary for Health to have the PHS Interagency Group to Monitor Vaccine, Production, Development, and Usage prepare the report.

In the process of gathering information for this report, we met with representatives of the organization, Dissatisfied Parents Together, and private individuals at a public meeting held on April 26, 1983. We appreciate the concern expressed by parents at that meeting. A transcript of the meeting and copies of subsequent submissions are included in the report.

I am pleased to have the opportunity to appear before you to discuss the Interagency Group's Report on Pertussis and Pertussis Vaccines. In addition to providing factual information, the Interagency Group has made recommendations pertaining to each of the seven items mentioned in S. 2950. In our presentation today we will address each of the items, indicate the recommendations made by the Interagency Group, and describe to you what progress has been made and what future developments may be expected.

The first item we addressed is:

1. DIAGNOSIS, REPORTING, AND RECORDKEEPING CONCERNING THE INCIDENCE AND SEVERITY OF PERTUSSIS AND SIGNIFICANT ADVERSE REACTIONS TO PERTUSSIS VACCINES.

The news reports of several weeks ago of a pertussis death in the Washington area serve as a reminder that whooping cough is still very much with us. For example, in this area alone, Maryland has reported 15 cases during the first 26 weeks of this year. For the same period, Virginia has reported 41 cases, with one death. Nationwide, the Centers for Disease Control, (CDC), has received reports of 891 cases, for the first 26 weeks of this year.

Pertussis diagnosis. Although the majority of whooping cough cases in which the causative agent can be identified are caused by Bordetella pertussis, other organisms for which the vaccine is ineffective can also cause the syndrome. Precise laboratory tests are required to define the full spectrum of illness caused by this organism as well as to evaluate vaccine efficacy. Current diagnostic tests are technically difficult or have an unacceptably high frequency of errors. Most cases are diagnosed on clinical grounds alone.

Recommendation:

- Develop improved bacteriologic and serologic diagnostic techniques.

The CDC is developing improved ways to recover the etiologic bacterium from clinical specimens. These techniques will be evaluated in Indonesia which, based on past experience, is expected to have frequent cases of pertussis in the late summer of 1983. Other more specific DNA-based tests for rapid diagnosis are in the early developmental stages. The Food and Drug Administration (FDA) has developed a potentially more accurate serologic test which is now undergoing evaluation in collaboration with CDC using specimens collected during an investigation of an outbreak in Colorado late last year. Preliminary results indicate this test for specific immunoglobulin A is useful as an epidemiologic tool.

Pertussis Reporting and Recordkeeping. Pertussis is officially required to be reported by agreement of all fifty States, but we believe underreporting is substantial. Since the degree of underreporting is likely to be relatively constant, the data are felt to give an accurate indication of trends of disease incidence. A precise count of the pertussis cases in this country cannot be easily achieved, but reporting can be improved.

Recommendation:

- Develop a standardized clinical case definition of pertussis for reporting purposes.

Planning is under way by CDC to conduct epidemiologic studies that will lead to the development of a standardized case definition as well as a determination of the true incidence rate of pertussis, pertussis vaccine efficacy, the effects of vaccination and antibiotics on disease severity, rates of complications of disease and the occurrence of adverse events following vaccination. Discussions have begun with States for the selection of suitable sites. This study is anticipated to be completed by the end of 1985.

Recommendation:

- Increase reporting and completion of individual case record forms.

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CDC has completed revisions and expansion of the Pertussis Case Report Form and the Pertussis Case Household Report Form intended to increase both the comprehensiveness and completeness of the information on reported pertussis cases. Completion of these forms on reported cases will enable an accurate assessment of the full impact and burden of the morbidity and mortality of pertussis disease. Their use by states in case investigations is planned to begin January 1984.

In the 4-year period, 1979-1982, CDC's supplementary surveillance system received reports of 2,477 cases of pertussis from 42 States. (This system consists of data obtained from completed Pertussis Case and Pertussis Household Report Forms.) The 2,477 case of pertussis reported through this system represent approximately 39 percent of the total number of pertussis cases reported to CDC by the States during that period. Evidence that this system is improving steadily is reflected in the fact that 66 percent of the individual reports were received in 1982 as compared with 20 percent in the earlier years (1979-81).

Recommendation:

- Increase investigations of disease in both outbreak and non-outbreak settings.

CDC is revising its FY 1983-84 recommendation to CDC grantees of Immunization Projects to include a request that at least 80 percent of all reported cases of pertussis have the Pertussis Case Report Form completed.

Investigations of outbreaks were undertaken in both Colorado and Maryland during the last year to further define the efficacy of vaccine and the epidemiology of pertussis.

Adverse Vaccine Reactions. Many conditions occur spontaneously in infants which make it difficult to determine whether association of these conditions with pertussis vaccine is by chance alone or is caused by the vaccine. This is particularly true of convulsions. Approximately 5 percent of all children will have a febrile or non-febrile seizure before reaching their seventh birthday. Thus, the incidence rate of seizures is highest during the age period that coincides with administration of pertussis vaccine. This makes assessment of vaccine-related events particularly difficult. Pertussis vaccines have been associated with fever, fretfulness, and inflammation at the site of injection, as well as more serious problems such as convulsions and encephalopathy, with or without permanent brain damage.

Suspected adverse events are reported by private health care providers or the manufacturers of the vaccines principally to the FDA or to CDC. A more formal system of surveillance exists for vaccines administered in the public sector. The Federal Important Information Statement requests reports on all persons who experienced an illness suspected as being an adverse reaction and who sought medical attention. The statement specifies that such events should be reported to local health

departments. We must again emphasize that serious illness attributed to pertussis vaccine are also found in unvaccinated children. Valid data on the frequency of adverse events following vaccination can be obtained only by a carefully designed scientific study comparing the frequency of such events in vaccinated and unvaccinated children. Such a study is presently being planned by CDC.

Recommendation:

- Improve reporting of adverse events to manufacturers, Office of Biologics (OB), and CDC.

FDA, OB will continue to work with and support educational efforts, through organizations such as the American Academy of Pediatrics and Advisory Committee on Immunization Practices, aimed at increased awareness of the desirability of reporting suspected adverse events by health care professionals. FDA has initiated a review of its past experience with the mechanisms used to stimulate reporting of adverse reactions to drugs to determine whether any of them can be applicable to DTP; this should be completed by November 1, 1983.

Recommendation:

- Maintain close communications about adverse events between manufacturers and OB.

Since April 1982 commercial manufacturers of vaccine have been reporting to OB, on a voluntary basis, all suspected adverse events following DTP vaccination which are reported to them.

Recommendation:

- Devise followup evaluations of children described as having "serious" reactions in recently reported U.S. studies.

FDA will convene an expert group of consultants in the fall of 1983 to review those studies and to advise OB on the best approach to followup.

Recommendation:

- Increase efforts to ensure full discussion about vaccine risks and benefits between parents and providers.

Although FDA does not have authority to impose mandatory disclosure requirements on the practicing physician, it will encourage discussions with patients through direct and indirect educational efforts such as the forms provided by American Academy of Pediatrics and by articles in the FDA Consumer and the FDA Drug Bulletin.

To assure maximal provider awareness of vaccine risks, further review and discussion within PHS and with non-government groups will be undertaken by the FDA during the regularly scheduled meetings of groups such as the American Academy of Pediatrics and the Advisory Committee on Immunization Practices during the course of the next year. If there is a consensus that the labeling of the vaccine or the package insert should be revised, FDA will take steps to require those revisions.

Recommendation:

Increase efforts to ensure full awareness on the part of physicians as to vaccine risks and benefits.

In addition to working with professional organizations such as the American Academy of Pediatrics and the Advisory Committee on Immunization Practices, FDA is planning to undertake a special education effort including an article in the FDA Drug Bulletin following the review of the various advisory groups.

CDC has developed two comprehensive information documents on pertussis disease and pertussis vaccine: one for health care providers, the other for parents. The document for providers reviews the clinical characteristics of pertussis disease, the current epidemiology of pertussis, pertussis vaccine safety, current policy, a report of the surveillance of adverse events following vaccine administration by public providers for the period 1978-1981, and a representative bibliography. The second information document provides the same information in a question/answer format using lay terms to parents or

lay persons making individual decisions about immunization. These documents were made available to all State and Territorial Epidemiologists and Immunization Directors who are responsible for public sector delivery of immunizations as well as to the American Academy of Pediatrics for use among private practitioners. Important Information Statements have also been made available to the American Academy of Pediatrics.

Recommendation:

- Improve followup evaluations of patients reported as having serious reactions.

CDC has revised the guidance to Immunization Projects to require the improvement of the monitoring of adverse events following vaccination. Revision of the Federal Report of Illness Following Vaccination form is currently in progress. The revision will increase the comprehensiveness of the information provided and will extend the period of patient monitoring of cases without residual effects to 30 days from the present 7 days, and institute periodic followup for 2 years of those with residual effects. Review of the 1980-82 data on adverse events following vaccination is in process. The review includes analyses of the quantity and quality of the data and the mechanisms by which it is collected. These data will be published as a surveillance report by November 15, 1983.

CDC has convened a Steering Committee of Immunization Project and Regional Office representatives to provide guidance on the monitoring system of adverse events following vaccination and to define ways to improve the system, including followup evaluation of persons reported as having had serious reactions.

Mechanisms for CDC and FDA computer-based exchanges are being explored to enhance the ability of either Agency to become rapidly aware of significant findings from adverse events reports.

Since no means are currently available to determine the role of vaccine in adverse events, the CDC is preparing a prospective study to allow the assessment of attributable incidence rates of adverse events following vaccination for vaccines currently recommended in childhood.

I will now discuss the second item we were asked to address. Some of these activities are also relevant to item 3, and will also be discussed under that heading.

2. AVAILABILITY OF TECHNIQUES FOR THE PURIFICATION OF, OR EXTRACTION FROM, EXISTING PERTUSSIS VACCINES, IN ORDER TO REDUCE THE REACTOGENICITY OF SUCH VACCINES WITHOUT RENDERING SUCH VACCINES UNABLE TO MEET APPLICABLE POTENCY STANDARDS.

A number of techniques have been developed by various groups, including the FDA, for the isolation and purification of pertussis components that are potentially less likely to produce adverse effects. These components appear to be candidates for testing as immunogens, which are substances that may provoke antibodies. A vaccine produced in Japan which contains only soluble antigenic material has been studied more thoroughly than any other candidate material. However, there is little published information available on the vaccine and no large scale efficacy trials have been conducted.

Recommendation:

- Support continued research to define and purify protective antigens.

The extramural and intramural programs of the National Institute of Allergy and Infectious Diseases (NIAID) currently support three research grants applicable to the definition and purification of protective antigens. Two relate to the study of the biologic effects of an enzyme that may be a candidate immunogen. The third relates to the study of the genetics and growth requirements of Bordetella pertussis to develop production methods which will provide more stable antigens.

Two NIAID intramural investigators are investigating antigens of pertsussis. The NIAID plans, in the near future, to expand the present effort to apply the latest technologies in molecular biology, including

monoclonal antibodies and recombinant DNA techniques, for investigations leading to the development of a "third-generation" pertussis vaccine composed of gene-specified subcellular components or synthetic antigens.

FDA is continuing its research on the purification of antigens of B. pertussis. In the past several years, OB investigators have prepared experimental vaccines containing highly purified proteins that have been shown to be protective in experimental animals. In addition, FDA is conducting research directed toward improvement of techniques for assaying antibody levels and vaccine potency.

Researchers at the National Institute of Child Health and Human Development (NICHD) are currently working on the production of an acellular vaccine, which might prove to have minimal side-effects while still provoking good antibody responses.

Recommendation:

- Make funds available for one or more contracts for development of improved vaccine.

A request for proposals for the development of an acellular pertussis vaccine was advertised by the NIAID on February 21, 1983. Proposals in response to this request have been reviewed and one contract award is planned for fiscal year 1983. It is expected that this contract will lead to a new candidate DTP vaccine within 2 to 3 years. Testing for safety, antigenicity and efficacy must then follow.

Recommendation:

- Collaborate with private industry in testing new vaccines.

The NIAID supports four vaccine evaluation units and has offered its services for safety and antigenicity testing of any new acellular vaccine developed by commercial manufacturers. One U.S. manufacturer is seeking an agreement with a Japanese manufacturer to obtain bulk pertussis vaccine to combine with its own diphtheria and tetanus toxoids. A clinical protocol has been developed by the NIAID vaccine evaluation program; the manufacturer and NIAID are currently planning to file an Investigational New Drug (IND) request (to be held by NIAID) for this vaccine. Phase I testing to study safety and antigenicity is expected to begin in late 1983. In addition, other U.S. and foreign manufacturers are working on versions of an acellular vaccine. NIAID staff has discussed similar collaborative studies to be done when these vaccines become available. FDA will be assisting in these clinical trials by conducting selected antibody assays and various tests of vaccine potency.

The third item we were asked to discuss concerns the following:

3. AVAILABILITY OR DEVELOPMENT OF PROCEDURES OR TECHNIQUES FOR IDENTIFYING CHILDREN, OR CATEGORIES OF CHILDREN, WHO MAY BE SUSCEPTIBLE TO SIGNIFICANT ADVERSE REACTIONS TO PERTUSSIS VACCINES.

The Advisory Committee on Immunization Practices and the American Academy of Pediactrics Committee on Infectious Diseases have identified contraindications to receiving pertussis vaccines. One major contraindication listed by both groups is the history of having had a severe reaction to a preceding dose of vaccine. In Britain contraindications include a history of epilepsy in a child or in the child's family or a history of reactions to pertussis vaccine in another family member. It has been suggested that it may be possible to develop a laboratory test to predict whether a severe reaction to pertussis vaccine is likely to occur. Some basis for this possibility stems from studies with a mouse model by which the investigators have demonstrated that genes in the major histocompatibility complex correlate with the ability to induce encephalopathy. Researchers in England have begun studies of children who develop complications from pertussis vaccine. They hope to identify a genetic marker in humans which may help to identify a subpopulation of children who are at greater risk of reactions to the vaccine. If successful, the practicality of such tests, however, would still have to be determined before the public health value of the test could be assessed.

Recommendation:

- Discuss again with the Advisory Committee on Immunization Practices and the American Academy of Pediatrics present recommendations regarding personal and family history of convulsions and family history of reactions as contraindications.

The bases for the current recommendations of the Department of Health and Social Security, Britain, and those of the Advisory Committee on Immunization Practices and the American Academy of Pediatrics are under review. After review by CDC, the results of this review are to be presented to the Advisory Committee on Immunization Practices at its meeting on October 18-19, 1983.

A meeting was held at CDC in June 1983 with Dr. David Miller, Director of the British National Encephalopathy Study, to further define the characteristics of the patients who developed encephalopathy with and without permanent damage in terms of their personal and family history of convulsions and their family history of reactions to pertussis vaccine. Further analysis of the data is planned by CDC in collaboration with Dr. Miller.

Recommendation:

- Support further research for predictors of adverse vaccine reactions.

The feasibility of conducting retrospective HLA studies in humans in the United States is under review by CDC and NIAID.

The fourth item is:

4. CURRENT PUBLIC AND PRIVATE EFFORTS TO DEVELOP AND DEMONSTRATE CLINICALLY A PERTUSSIS VACCINE WHICH IS SAFER THAN THE PERTUSSIS VACCINES CURRENTLY USED IN THE UNITED STATES.

The NIAID has in place a mechanism for the Phase I testing of the safety and antigenicity of new vaccines, including pertussis. There are vaccine evaluation units at Vanderbilt University, University of Rochester, Baylor University, and Marshall University. The OB, FDA will be participating as indicated earlier by testing a variety of laboratory and clinical specimens. There are also three commercial manufacturers of pertussis vaccine in the United States. Each manufacturer has stated that they have a program in place to improve the currently marketed vaccine.

Recommendation:

- Intensify support for development and testing of improved vaccines.

NIAID has offered the use of its vaccine evaluation units to qualified investigators in both the public and private sectors for testing of any candidate immunizing material available. Clinical protocols for this evaluation have been developed and distributed to other evaluation units so that a testing program can be quickly mounted in all facilities.

Recommendation:

- Make funds available for one or more vaccine development contracts.

As mentioned earlier, on February 21, 1983, NIAID released a request for proposals for the award of a contract for the development and production of an improved acellular vaccine. One such contract is to be awarded in fiscal year 1983. It may be 2 to 3 years before the purified vaccine will be ready for human testing in the evaluation units.

Recommendation:

- Determine if Japanese type acellular vaccine could be used in this country.

It has not been possible to obtain DTP vaccine manufactured entirely in Japan because of the concern of the Japanese manufacturers about liability. One U.S. manufacturer, however, is working with the Japanese manufacturer previously mentioned to obtain bulk material made in Japan. It will be combined with diphtheria and tetanus toxoids and packaged by the U.S. manufacturer as noted above. Other U.S. and foreign manufacturers are developing acellular pertussis vaccines which may be similar to the Japanese product; these materials will also be tested as they become available.

Recommendation:

- Identify study sites overseas for field trials of improved vaccine.

NIAID and CDC staff have had preliminary discussions with investigators in Britain and in Sweden with regard to possible future vaccine efficacy trials, if overseas study sites are needed at a future date. Trials in the United States do not appear practical since vaccine acceptance is high and disease incidence is low. Vaccine acceptance is still low and disease rates high in Britain, and efficacy trials may be possible there if a new vaccine is shown to be safe and antigenic in U.S. studies. There has recently been a renewed interest and

acceptance of vaccination in Britain and consequently, the situation there may change. Investigators in Sweden have been compiling disease incidence data to determine the feasibility of trials in that country. Officials of the World Health Organization have also expressed interest in collaborating in trials in various countries with high incidence rates of pertussis and work is underway to identify additional sites for efficacy trials.

The fifth issue concerned:

5. THE ASSOCIATION, IF ANY, BETWEEN PERTUSSIS VACCINATION AND SUDDEN INFANT DEATH SYNDROME AND THE NEED FOR FURTHER STUDY OF SUCH ASSOCIATION.

The possibility that DTP vaccination might cause SIDS has been raised in several publications, most of which represented uncontrolled studies. Perhaps the most definitive study is the multi-center study funded by the NIH. Analysis of approximately one-half of the study population has been completed. The NIH study in 1982 revealed a lower frequency of DTP vaccination in SIDS cases than in their living controls. A study in Britain also indicated that SIDS cases were less likely to have been vaccinated than were their living controls.

Recommendation:

- Complete analysis from NICHD, SIDS Study.

A preliminary analysis of the entire study population with regard to history of DTP vaccination will be available in the fall of this year.

The sixth item concerned:

6. THE CREATION AND OPERATION OF A FEDERAL COMPENSATION PROGRAM FOR INDIVIDUALS WHO ARE SERIOUSLY INJURED AS A RESULT OF ADVERSE REACTION TO THE PERTUSSIS VACCINE, INCLUDING AN EVALUATION OF EXISTING COMPENSATION PROGRAMS IN CALIFORNIA AND IN OTHER COUNTRIES.

Within the United States, there has been extensive consideration of issues relating to establishment of a compensation system. The American Academy of Pediatrics has drafted a specific proposal for compensation and vaccine-related damage. To date, the Department of Health and Human Services has not adopted a position regarding establishment of a compensation system for individuals injured by vaccination, but we are continuing to consider this issue.

The final item we were asked to address concerns:

7. ADMINISTRATIVE AND LEGISLATIVE CHANGES WHICH ARE NECESSARY TO CARRY OUT PURPOSES OF THE ACT.

The two major challenges that we face in the prevention of pertussis are: first, to educate the medical community and the public as to the risks of pertussis disease and the benefits and risks of pertussis vaccine, and second, to provide a pertussis vaccine which has minimal adverse effects. Both of these challenges can be met and progress continues to be made under our present administrative structure and under present legislative authority.

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In summary, pertussis remains a serious public health threat. The United States is continuing to seek to increase our immunization levels. The American Academy of Pediatrics' Committee on Infectious Disease and the Public Health Service Advisory Committee on Immunization Practices continue to recommend pertussis vaccination. The lesson learned from Britain during the past few years is clear: The benefits of pertussis vaccination far outweigh the risks.

We accept the responsibility to continue to reduce those risks.

This concludes my formal statement. My colleagues and I will be glad to respond to any questions you may have.

Senator HAWKINS. Thank you.

On page 3 of the report you say, "It's widely acknowledged that there is substantial underreporting of pertussis in the United States, even though the condition is notifiable in all 50 States." Do you have any idea how we can enforce the reporting?

Dr. DOWDLE. Of pertussis itself?

Senator HAWKINS. Yes.

Dr. DOWDLE. Dr. Bart, would you mind responding to that question?

Dr. BART. Underreporting is not unique for pertussis. There is varying between 50 and 70 reportable diseases in the United States which each of our States maintain the responsibility for reporting nationally, keeping such records and making such reports. The utility of total ascertainment of every case of pertussis may be quite limited, and the cost and effort required to report every such occurrence may not be desirable. We have sufficient information to appreciate secular trends, to be able to interpret the epidemiologic significance of increases and decreases and to understand the efficacy of vaccination within specifically studied populations. Understanding better the efficacy of disease is best done in specific outbreak situations and not necessarily through the routine reporting of every individual case.

We have, however, made very significant efforts to both alter our surveillance systems through the improvement of the routine case investigation form, so that both the quality and quantity of the data that is currently being made available will be enhanced. We have very clear evidence that that has occurred during 1982.

Of all cases reported to the Centers for Disease Control during the prior 5-year period which were reported only as age and sex, we now have an increase from some 39 percent of the prior 5-year period to now 66 percent of all reported cases having a completed body of quantitative as well as qualitative demographic and disease information available. Therefore, there has been very significant progress. We are looking forward to the next year improving that

by additional increments, both through the cooperation of States and through the enhancement of these forms.

Senator HAWKINS. At the 18th Annual Conference on Immunization one of the speakers made the point that, given the lack of confidence in the pertussis vaccine, it is not sufficient to simply demonstrate that a vaccine continues to protect against disease because this only looks at half of the question. It is necessary to describe the nature, the frequency and relatedness of illnesses which are associated with immunization. All of these factors are dependent upon adequate reporting, recordkeeping, and close marketing surveillance. I know that both CDC and the Office of Biologics at FDA have postmarketing surveillance systems for illnesses following immunization.

Isn't the current system used primarily as an early warning system for detecting very unusual reactions or an increase in expected reaction? It is not designed to provide what the layman would call reliable incidence rates of reactions following immunization?

Dr. DOWDLE. To some extent, of course, that is true. That has been the thrust of the surveillance program for adverse reactions. However, there are really two basic areas with which we should be concerned for surveillance and for reporting of adverse reactions, those being the public and the private sectors.

Our opportunities are best in the public sector for getting the types of information that we need which would give us rates, an accurate estimate of reported suspected adverse reactions which would allow us to make the necessary decisions. Public sector information would make available to us numerator as well as denominator data.

The work being done in the public sector is being done at the moment in CDC, and Dr. Bart might want to respond further to that.

Dr. BART. I think the issue of total ascertainment may be what you are alluding to; that is, it is clear, very clear, that total ascertainment is not being obtained for all adverse events. We do, however, have in place a sentinel system which allows us to do what you described; that is, to appreciate unusual events and the occurrence by vaccine and by lot of specific occurrence of events.

The enhancement of that system would only have limited value and would be very costly. Again, it is very appropriate for us to use that as a sentinel system to then decide where specific investigations, both epidemiologic and clinical, would be appropriate.

Senator HAWKINS. Is the current system volunteer, Dr. Bart?

Dr. BART. I am sorry?

Senator HAWKINS. Is the current system a voluntary system?

Dr. BART. The current system in the public sector is a voluntary system in which all States, however, comply. The system is dependent and related to the important information statement which all parents are expected to read prior to the receipt or request of vaccine for their child. Appended to the bottom of the important information statement is the request, and a signature is required.

Associated with that important information statement is a telephone number, a name, and a statement that any perceived adverse event which is thought to be related within 30 days of the

receipt of vaccination be reported to a specific individual at the local health department where the vaccine is received. In spite of the fact it is a voluntary system within the public sector, it is complied with essentially uniformly because of its relationship with the important information statement.

Senator HAWKINS. Do you have a copy of that form?

Dr. BART. Yes, we do.

Senator HAWKINS. That is given to those parents who get the vaccine from a public clinic?

Dr. BART. That is correct.

Senator HAWKINS. What percentage is that?

Dr. BART. Nationally, approximately 50 percent of all vaccine administered in this country is administered through the public sector.

Senator HAWKINS. Inasmuch as HHS does not have consolidated Federal contracts for the purchase of DTP vaccine, only a small amount of DTP is actually purchased with HHS Federal funds and, therefore, subject to that mandatory use of the important information consent form you are discussing, which advises the vaccine recipient of the risk of vaccine and where to call should problems arise.

Do you know how many States are using the form?

Dr. BART. It is true that we do not have a consolidated Federal contract for the purchase of DTP vaccine. However, most States have recognized the value of the important information statement and have used it uniformly for the administration of all vaccine. I do not have a specific number of States that use it. It is our understanding that most States do.

Senator HAWKINS. Has the Joint Commission on Prescription Drug Use made any recommendations regarding the advisability of developing some type of active and mandatory postmarketing surveillance system to collect and analyze the data regarding patients' reactions to drugs that have been released for marketing?

Dr. DOWDLE. Dr. Petricciani from FDA will respond to that.

Dr. PETRICCIANI. Senator Hawkins, I am not aware that they have, but we will respond to that in writing. We will find out.

Senator HAWKINS. Thank you. I would appreciate that.

[The material referred to, and supplied for the record follows:]

JOINT COMMISSION ON PRESCRIPTION DRUG USE

RECOMMENDATIONS

Although the Commission has made 31 major conclusions and/or recommendations and many lesser ones, we consider the below 5 our most important. Reasoning to support each of these statements is provided in the body of our report.

1. A systematic and comprehensive system of post-marketing drug surveillance should be developed in the United States.
2. Such a system should be able to detect important adverse drug reactions that occur more frequently than once per thousand uses of a drug, to develop methods to detect less frequent reactions and to evaluate the beneficial effects of drugs as used in ordinary practice. New methods will have to be developed for the study of delayed drug effects, including both therapeutic and adverse effects.
3. An integral function of the post-marketing surveillance system should be to report the uses and effects of new and old prescription drugs.
4. Recognizing the progress that the FDA has made in the area of post-marketing drug surveillance in the last three years, the Commission recommends that PMS should be a priority program of the FDA and that the FDA should continue to strengthen its program in this area.
5. A private, non-profit Center for Drug Surveillance (CDS) should be established to further the development of a post-marketing surveillance system in the United States. This Center should foster cooperation among existing post-marketing surveillance programs, develop new methods for carrying out surveillance, train scientists in the disciplines needed for doing post-marketing surveillance, and educate both providers and recipients of prescription drugs about the effects of these drugs.

VI. CONCLUSIONS AND RECOMMENDATIONS

1. Post-marketing surveillance can be used to develop information about prescription drugs that is unavailable from pre-marketing studies but necessary and/or useful for the clinical practice of medicine or ongoing regulation of drugs. Existing postmarketing surveillance programs should be coordinated with new programs to form a comprehensive system.

2. The purpose of post-marketing surveillance is to detect important drug effects earlier than would otherwise be possible. The surveillance, per se, or its results will not and cannot be used to change the biological properties or effects of drugs, but they can be used to minimize the harmful consequences and maximize the optimal use of drugs.

3. Certain risks posed by a PMS system must be recognized, accepted, and addressed, although they are judged by the Commission to be far outweighed by potential benefits.

4. Highest priority in a PMS system should be given to surveillance of new chemical entity prescription drugs, delayed or slowly developing drug effects, commonly used drugs, populations in which drug effects are not well documented, certain important medical events (e.g., births, deaths, etc.) and their relationship to drug use, and patterns of prescription drug use. Other, but secondary, priorities should include the study of: certain important non-prescription drugs, the drug-taking practices of patients, the frequency of given drug effects, dose-response relationships, the characteristics of patients who experience certain effects as compared to those who do not, the relative risks and benefits of individual drugs, changes in frequencies of drug effects over the course of time, and the comparative efficacy and safety of different drugs within the same class.

5. PMS must operate, to the maximum extent possible, in a setting of actual medical practice. In the majority of instances, PMS should be concerned primarily

with drugs marketed without special restrictions beyond those already enforced for drugs of certain classes. Data collection for PMS should not interfere with the normal delivery of health care.

6. A PMS system will require both an alerting (hypothesis-generating) mechanism and a confirming or rejecting (hypothesis-testing) mechanism. Hypotheses must be recognized as suggestions about cause-effect relationships and not as established fact.

7. An hypothesis-generating mechanism should ideally have access to all animal and clinical data about a drug.

8. A great deal of selectivity will be required for judicious decisions about which of the available hypotheses to test.

9. PMS must insure that great attention is paid to research design and to the sequence of studies. Particular attention should be paid to the validity of the methodology and to the sample size required. Possible types of study are prospective or retrospective, experimental or non-experimental, controlled or uncontrolled, cohort or case-control, studies of drugs or of events, and studies of prophylactic, therapeutic, or diagnostic drugs.

10. Development of new methodology for study of drug effects must be a high priority for the PMS system.

11. The drug effects requiring study will be expected toxicity, unexpected toxicity, intended efficacy and unintended efficacy.

12. Currently available methodology can be used to study expected or unexpected toxicity and unintended efficacy, successfully detecting events that occur with a frequency of at least one event per 1000 exposures. Less frequent events (e.g., one in 10,000 uses) can be detected less reliably.

13. The Commission strongly recommends against PMS that ignores the determination of intended efficacy and of long-term drug effects.

14. An intensive system of surveying the medical literature should be established and particular attention given to a systematic review of data comparing drug responses in various countries.

15. A PMS system should develop methods of seeking and receiving brief reports from large numbers of health professionals.

16. Prospective, non-experimental cohorts that are long-term and lifelong, if possible, should be established for PMS studies.

17. Liaison between the various components of a PMS system will be necessary. This would require development of a standardized terminology for describing PMS and for use in PMS.

18. Reports must be prepared, published and distributed to all parties involved in or affected by PMS. Multiple types of reports will be necessary, tailored to the differing needs and interests of the recipients.

19. For a prescription drug surveillance system to be effective, it must have the confidence of the public at large, including health care providers and patients. This confidence must extend not only to the validity of the information generated, but also to the manner in which the information will be used.

20. In order to maintain trade secret protection for manufacturers without prejudicing the PMS system's public and academic accountability, only the FDA should have the power to require the disclosure of such secrets. Because of this restriction, the FDA must assume responsibility for reviewing this trade secret data for any hints of drug effects in man that it may contain.

21. In order to protect patient confidentiality, individually identifiable information should be kept strictly confidential by any PMS system unless patients specifically authorize release, with only the following exceptions:

a. Such information could be released to organizations engaged in similar research if an express finding with supporting written statements is prepared documenting that such disclosure is necessary and identifying the individual receiving the

information. Such organizations must have comparable guarantees of confidentiality as the organization releasing the data. Redisclosure by the receiving organization would be prohibited without written approval of the original organization.

b. Disclosure could be made to a properly identified recipient pursuant to a bona fide medical emergency.

c. Both patient and provider must have access to their own identifiable data and the ability to make corrections or amendments.

22. Given the fact that the law is developing on the issue of provider liability for disclosing patient identifiable medical records, the Commission recommends that the organizations concerned with PMS review the issue of liability as they begin to undertake PMS functions.

23. In order to assure adequate security for data gathered, a PMS organization should:

a. Maintain only that information which is relevant and necessary to accomplish the purpose.

b. Maintain all records used in making any decisions about an individual with such accuracy, relevance, timeliness, and completeness as is reasonably necessary to assure fairness to the individual in the determination.

c. Establish administrative, technical, and physical safeguards to insure the security and confidentiality of records.

24. The value for PMS of a limited shield law is recognized. Such a law would specify that identifiable information of the patient or provider submitted voluntarily to a PMS organization could not be admissible as evidence in a medical or product liability action, and might remove a deterrent to voluntary reporting. Even without such a law however, the PMS functions of the CDS should commence and the results should be used to define whether evidence needs to be gathered to support the need for and formation of shield law in order to have an optimal PMS system.

25. A national Center for Drug Surveillance (CDS) is necessary in the United States.

26. The objectives and functions of the CDS should be to educate scientists, prescribers and the public, to perform and encourage research into drug effects and to promote cooperation among all existing PMS programs.

27. In using its resources, the CDS must be strictly accountable for fairness, scientific accuracy, and honesty.

28. The activities of the CDS should not unnecessarily duplicate the functions of other organizations engaged in PMS activities, whether public or private.

29. The CDS should be a private, non-profit, non-regulatory organization with a full-time staff and a physical facility located in an environment that can support and be supported by academic endeavors.

30. After five years, there should be an external review of the effectiveness of the CDS. If the projected benefits from the CDS are not realized, the CDS should be abandoned.

31. Support for the CDS should be in addition to, not instead of, added support for other worthwhile PMS activities.

Senator HAWKINS. Everyone admits that underreporting is a problem. We all know that. The Morbidity and the Mortality Weekly Report states that only 20 percent of the cases that were reported to MMWR were reported through the supplemental surveillance system. In its September 1981 report on Federal vaccine and immunization policies, the Office of Technology Assessment recommended several policy options designed to improve the postmarketing surveillance of adverse reactions to specific vaccines and intensify the Federal effort to encourage voluntary reporting of such reactions by the private sector.

One option was to authorize the FDA to require manufacturers to conduct postmarketing surveys of specific vaccines. The other policy option was to convert CDC's passive, voluntary case reporting system to an active mandatory system to monitor the reactions to monitor vaccines used in public programs.

Do any of you have comments on any of these recommendations?

Dr. DOWDLE. Whereas we are certainly sympathetic to the need to get complete reporting, we have to keep in mind, though, that there is a limit to how much complete reporting can do for you. It is important to have good numerator data and good denominator data. We are then able to get some suggestion of rates, even though we are dealing with only suspected adverse reactions.

Just reporting of reactions along without good denominators, is not all that helpful. If we can get a very tight study done in the public sector, that could give us the information that we are looking for. For epidemiologic purposes we don't need every case to be reported.

Senator HAWKINS. Do we have adequate tests for toxicity that has been shown to be correlated with reaction in small infants?

Dr. DOWDLE. You are referring to animal toxicity tests?

Dr. Petricciani?

Dr. PETRICCIANI. As indicated in the report, Senator Hawkins, there are a variety of animal tests which have been proposed to assess toxicity in infants, but the net consensus, I think, is that the current tests which are applied to the vaccine are about the best that is currently available, although there are some exploratory studies. For example, the study in California using genetically engineered mice which may be predictive of a special reaction in a special group of children is being explored and supported by the NIH. At this time we do not feel that there is an explicit animal test which would be predictive of some of the side reactions which occur with low frequency.

Senator HAWKINS. You are monitoring the California program?

Dr. PETRICCIANI. Yes. NIH is continuing to fund that study and we are following it.

Senator HAWKINS. If adverse reactions occur as a result of hypersensitivity in an infant, what can be done to predict and prevent them?

Dr. DOWDLE. In the report we refer to some studies that are now taking place that look at genetic predictors of sensitivity to adverse reactions to the vaccine. That effort up to now has been restricted to animal studies. We have no idea whether such techniques can be actually applied to the human population. In addition, we have no idea, even if it did work, that it would be of application in the public health sector, because of the present expense of such tests and the difficulty in conducting tests on all vaccines.

We would support the research, as the NIH continues to do, but we will have to wait and see what turns out before we can determine whether it might be useful.

The other side of that, though, is whether there are predictors in the sense of history, and that, I indicated earlier, is something that the CDC is reviewing and will be rediscussing with the Advisory Committee on Immunization Practices this fall. One possibility is to consider the English system of whether history of reaction in a family would be predictive.

Senator HAWKINS. With regard to these genetic marker studies in England and California, you state in your testimony that, "If successful, the practicality of such tests would still have to be determined before the public health value of the tests could be addressed." Would you explain what you mean by that?

Dr. DOWDLE. First, these are very difficult tests to perform. The so-called HLA markers are very expensive to determine. They are difficult tests and very time consuming. The question also is, at what level of predictability? In other words, would such tests detect 60 percent, 70 percent, or 100 percent of children at risk of adverse reactions? In many cases the predictability may only be an increased likelihood that a child might react.

Senator HAWKINS. On page 15, according to your report, a recalculation of the cost-benefit analysis was undertaken using the most recent incidence of disease complication information from the Brit-

ish and from the UCLA study of reactions. Could you summarize the results of the reanalysis?

Dr. DOWDLE. Yes.

Dr. Bart, would you like to respond to that?

Dr. BART. There have been two analyses that have been undertaken. One is not yet complete. One is based on our most recent ascertainment during the current year of adverse events.

The prior reanalysis, upon which the current recommendations of the Academy of Pediatrics and the Advisory Committee on Immunization Practices are based, suggests again that the benefits of offering pertussis vaccine to children continues to outweigh the risks of adverse events associated with the receipt of vaccine.

Senator HAWKINS. What has been the Japanese experience with the new acellular vaccine?

Dr. DOWDLE. Dr. Jordan, would you want to respond to that?

Dr. JORDAN. They have been using this acellular vaccine for several years. The Japanese traditionally immunize children at an older age group than in the United States. Our immunization age is based on the increased risk of disease in the younger child. That is the age group for which the vaccine is primarily indicated. Therefore, it has been difficult to translate the Japanese experience directly to U.S. usage because of the beginning of their vaccine program with the 2-year-old child.

They have recently begun to immunize younger children, beginning at 3 months, and we are trying to learn from them their experience immunizing children in this age group.

We are also trying to obtain from the Japanese specific data regarding the efficacy of the vaccine that they are now using.

Dr. DOWDLE. Dr. Petricciani might want to add to that as well.

Dr. PETRICCIANI. Several months ago we wrote to the director of the Japanese NIH asking for the kind of information that you just asked for. That is data specifically on the safety and efficacy of their current vaccine. The response from the director of the Japanese NIH was that they are in the process of reviewing their data, and that as soon as they are done with that analysis they will send it to us. We don't have that yet.

Senator HAWKINS. When was the request made?

Dr. PETRICCIANI. Two or three months ago.

Senator HAWKINS. Sometimes it is felt that a new vaccine should be offered to the American population on the basis of the information already derived from the Japanese experience? What is your response to that?

Dr. PETRICCIANI. To the extent that the data that we could obtain from the Japanese experience shows safety and efficacy, we would certainly be willing to review that as part of the review process for the approval of a new vaccine.

Senator HAWKINS. Your report states that you are pursuing negotiations with the Japanese manufacturer to purchase bulk acellular pertussis vaccine and to use their manufacturing process to produce an acellular pertussis vaccine in the United States. What is the status of those negotiations?

Dr. PETRICCIANI. Those negotiations actually are being conducted by one of the pharmaceutical manufacturers.

Senator HAWKINS. Not the Government?

Dr. PETRICCIANI. Pardon me?

Senator HAWKINS. Not the Government?

Dr. PETRICCIANI. Not the Government, although the Government was interested—that is, NIH and FDA were interested—in obtaining some of the Japanese vaccine for use in clinical trials here. The results of those negotiations were that the Japanese would not provide vaccine for us to use in clinical trials because of liability concerns.

In the private sector, a pharmaceutical manufacturer in the United States is pursuing those negotiations, and they are still in the process of that.

Senator HAWKINS. Dr. Bart, I understand that you presented a paper to the Biologic Workshop in February of 1982 entitled "Clinical Assessment of Acellular Pertussis Vaccine," which addressed the question of whether clinical studies of the safety and efficacy of a new pertussis vaccine would really even be required. Can you summarize the conclusions which you reached in your paper?

Dr. BART. I should clarify the fact that I was the second author on that paper, and it was a theoretical paper addressing the issue of sample size; that is, the size of population necessary to carry out such a vaccine trial and the incidence of disease that would be required in order to evolve substantive responses to that testing.

It is the conclusion of that paper that it would not be possible, feasible, or cost-effective to carry out such a vaccine trial in this country with the current incidence of pertussis, and that suitable other sites would be more efficiently sought after—should be more efficiently sought after.

Senator HAWKINS. In the paper you estimated that if the new acellular vaccine was anywhere from 30 to 90 percent safer, as many as 27 to 81 cases of permanent damage of children might be prevented by using the safer vaccine immediately. Hasn't the data on Japan's new acellular vaccine indicated that it is safer, as Dr. Petricciani has stated? We all know it is superior to the conventional pertussis vaccine.

Dr. BART. I think the theoretical calculation you just mentioned is, in fact, accurate. However, it is important to remember that the Japanese vaccine has not passed either safety or efficacy testing in this country. We have not had it available to test.

I believe that is accurately what Dr. Petricciani stated, that we do not have a vaccine available and it has not passed either safety or efficacy testing in this country. Therefore, it could not be put into the population, even if there were sufficient incidence in this country to test it.

Dr. DOWDLE. I might add that Dr. Petricciani referred to the formal letter which went forward several months ago, but that was the last in the line of a number of efforts that have been made on a personal level and investigator-to-investigator level to the Japanese to get access to the vaccine and also to the data.

In fact, there have been some earlier releases of laboratory data, but that is all the information we have to this point.

Senator HAWKINS. Didn't the Japanese offer the United States the opportunity to send scientists to Japan to study the vaccine?

Dr. DOWDLE. Yes.

Senator HAWKINS. Did we take advantage of that?

Dr. PETRICCIANI. As part of the response to our letter asking for safety and efficacy data on the vaccine, the Japanese responded that they would be willing to have representatives of either CDC or FDA go to Japan to go over the data once their analyses had been completed. Since we have not had their submission yet to us on the analysis, we have not asked anyone to go over to review it with them.

Senator HAWKINS. We have not? Is that what you said?

Dr. PETRICCIANI. Pardon me?

Senator HAWKINS. Did you say we have not?

Dr. PETRICCIANI. We have not sent anyone over to review the data with them because their analysis is not yet complete, although we have had individual scientists in Japan in various laboratory settings, and we have also had some Japanese scientists in our laboratories here.

Senator HAWKINS. They copy so many things of ours. I think it would be refreshing to do the reverse.

I understand that the National Institutes of Health issued a request for proposal or an RFP for the development of an acellular Bordetella pertussis vaccine and that the RFP was deemed necessary because of a belief in the scientific community that the current wholesale vaccine for pertussis has shortcomings which could be eliminated with more modern technology.

Are U.S. drug manufacturers interested in pursuing the development of new pertussis vaccine?

Dr. JORDAN. We have had communications from three of the manufacturers, as indicated in the report. They are working in their own laboratories with their own technologies to develop what they believe will be improved pertussis vaccine.

Senator HAWKINS. Were there any responses to your RFP?

Dr. JORDAN. Yes, Ma'am. We will be funding one new contract after it receives technical review August 4. Essentially, it is ready to go.

Senator HAWKINS. I was told that the Japanese drug manufacturers are quite reluctant to let their acellular vaccine be tested in the United States because that was the reason they invited us over there, because of liability concerns. We have more lawyers in this country than they do.

Won't we have the same problem with any new vaccine developed under the RFP?

Dr. JORDAN. It would depend on who would be the final producer. Our objective was to catalyze research efforts in this area beyond what the pharmaceutical manufacturers are doing themselves. Eventually, we will have to, if the successful bidder on this proposal wishes to distribute the vaccine nationally, arrange for commercial production and distribution. The commercial pharmaceutical firm that has made arrangements with the Japanese to import its pertussis vaccine in bulk, when it produces its product here, will then assume liability responsibility rather than the Japanese. That is why the Japanese were willing to negotiate with them rather than to provide the vaccine directly to us, so that we might test it ourselves.

Senator HAWKINS. What are the practical difficulties of clinical testing in the United States?

Dr. JORDAN. We are blessed with the fact that we have a pretty good vaccine now and very little whooping cough when that vaccine is properly used.

It is not possible to test a vaccine in the absence of enough disease to challenge the vaccine. You have to test the vaccine where the disease has occurred.

We have been discussing with the British the possibility of having a trial there because they are still having epidemics of whooping cough as a result of discontinuation of adequate vaccine. We may have to find other parts of the world where they are not so well served by pertussis vaccine to test the new vaccine.

Senator HAWKINS. Any recommendation about the possibility of a Federal compensation system for persons injured by vaccines has been avoided this morning. I realize you cannot speak for the administration on this issue without prior OMB approval. Most Senators realize that.

But didn't the Government's experience during the swine flu vaccination program clearly demonstrate that health programs can be seriously jeopardized when manufacturers and insurers merely follow sound business policy and stay clear of any risky venture?

Dr. DOWDLE. The Department is, in fact, looking into the compensation issue and has communicated with the Academy on their proposal.

Senator HAWKINS. I was pleased to see that the Department had conducted a study on the estimated economic cost of selected medical events known or suspected to be related to the administration of common vaccine. These estimates provide an important first step in quantifying the extent of the Government's liability for such morbidity and mortality.

In order to estimate the magnitude of the liability that the Government stands to incur should it decide to assume this responsibility, these unit cost estimates must be combined with incidence data on adverse effects. Are any studies currently in progress?

Dr. DOWDLE. Data have been collected on this. I must plead ignorance in that I am not personally involved. In fact, I do not think anyone else here on the Interagency Group is personally involved in that effort at the moment.

Senator HAWKINS. Do you have any knowledge as to whether any are planned?

Dr. DOWDLE. No; I do not. I am sorry.

Senator HAWKINS. We will find out.

Thank you so much for your coming forward today. We look forward to a progress report from you on the implementation of the steps you have recommended and working with you as we continue to solve this problem.

Dr. DOWDLE. Thank you very much.

Senator HAWKINS. The next panel of witnesses will consist of Dr. Martin Smith, representing the American Academy of Pediatrics, and Mr. Jeffrey Schwartz, representing the Dissatisfied Parents Together.

Dr. Smith and Mr. Schwartz, I know that both of you are very interested in improving the safety and effectiveness of childhood vaccines and you have dedicated many hours of your own personal time to pursue the possibility of Federal legislation to compensate

children who are injured by vaccines which are mandated under our State laws.

I look forward to hearing your recommendations regarding what components you feel are essential in establishing such a compensation program.

Jeff, if you would begin by giving your opening remarks, after that we will turn to Dr. Smith.

STATEMENT OF JEFFREY H. SCHWARTZ, PRESIDENT, DISSATISFIED PARENTS TOGETHER

Mr. SCHWARTZ. Thank you, Senator Hawkins.

I want to thank you and the committee for the opportunity to appear before you today and present the views of Dissatisfied Parents Together. I am here today both in my capacity as president of Dissatisfied Parents Together and as the parent of a vaccine-damaged child. I speak, not only for my own child, but through the organization, we hope to be the voice of the children who cannot speak for themselves.

We appreciate your willingness to hear that voice here today and previously. We thank the committee and you personally for your vigilance and oversight with respect to the vaccination program. We particularly appreciate your sponsorship of S. 2950 and insistence that the Department conduct the study that we have before us today.

With the consent of the committee, we would request that our written testimony be submitted for the record, along with the attachments, and I will try to summarize the major points.

Senator HAWKINS. Thank you.

Mr. SCHWARTZ. I would like to say a word about Dissatisfied Parents Together for those who may not be familiar with the organization. It is important to understand that we see four major needs:

One, a pressing need for safer pertussis vaccine.

Two, the need to reduce the risks of serious adverse reaction to the current wholecell pertussis vaccines by the adoption of certain critical safeguards. As long as we have to use the wholecell vaccine, these safeguards need to be in place.

Three, the need for an appropriate victim compensation system, which we will address later in the testimony, for those children who are seriously injured by the pertussis vaccine.

Also, the need to avoid what we call a "victim condemnation" system. We want to discuss this concept much more fully because we think that is a real and present danger.

Four, the need to develop and use an adequate basic information system both with respect to pertussis and pertussis vaccine reactions, so that the claims that the benefits of pertussis vaccine exceed the risks can be fairly evaluated.

The committee has been told today by representatives of the Health and Human Services Department that we have a pretty good pertussis vaccine. We would like to explore that assertion with you. From the standpoint of the many parents of children with severe damage as a result of this vaccine, the vaccine does not look pretty good.

To summarize some important points about Dissatisfied Parents together, however, we are not antivaccination generally or opposed to child immunization programs. We support properly structured disease prevention programs. We think that they are important. We are not focusing on vaccines other than the pertussis part of the DPT vaccine, although we recognize that it may be appropriate for the committee to do so. We are not indifferent to the dangers of pertussis disease. We acknowledge and are concerned about its dangers as much as we are about the dangers of the vaccine. We recognize that some of the most serious results of the disease and of a reaction to the vaccine can be very similar. Our hearts go out to the families who suffer what our children have suffered, whether it is from the disease or a reaction to the vaccine.

Finally, we are not advising parents to withhold the pertussis vaccine from their children. We neither oppose nor recommend pertussis vaccination at this time. We believe that this is a decision which should be made by informed parents after thorough consultation with their doctors, after consideration of the specific circumstances of their child's and the community's health, and after examination of accurate and complete information on the dangers, as well as the benefits of the vaccine. I will come back to elaborate this final point.

Turning now to our views on the HHS report, which the committee has received, we have not had a complete opportunity to go over it with a fine-tooth comb. We would like, therefore, to be able to submit more detailed comments for the record.

However, today we want to indicate that from the standpoint of Dissatisfied Parents Together the report has some good news and it has some bad news. The good news is, in part, that the HHS report, in its own indirect way, constitutes departmental acknoxledgment that there are significant problems with the wholecell pertussis vaccines and with the health care system that administers those vaccines. The other part of the good news is that in a general way the HHS report supports the overall goals of Dissatisfied Parents Together for addressing these problems. If you look at the report, it says basically, "Yes, we need a safe vaccine. Yes, we need more attention to high-risk children and contraindications to giving the vaccine. Yes, we need a better reporting system. Yes, we need to better inform parents. Yes, we need a better recordkeeping system. Yes, we need some attention, at least, to the issue of victim compensation. Yes, we need all these things—better surveillance and follow-up of reaction cases," and so on.

From our standpoint, at some level the report is good news. For the first time, the Department is on record as saying there is a real problem and the solutions in general—the goals, I should say—that Dissatisfied Parents Together has put forward as its program are the right goals. These are the goals that, I am happy to say, Senator Hawkins herself has recognized in her legislation. We are greatly appreciative of the recognition given in S. 2950 to the overall goals of Dissatisfied Parents Together.

Unfortunately, from our standpoint, the bad news in the report is quite bad. I want to start with the contention made by Dr. Dowdle of HHS that we met with HHS and they listened to us. One of the most distressing things about the report, from our

standpoint, is it demonstrates the remarkable closedness of the Department's approach to the pertussis vaccine problem.

Although a public hearing was, admittedly, held, there obviously was no "hearing" by HHS at the hearing. A careful comparison of the HHS report with the transcript of the opening statements at the hearing by HHS personnel, before any information was presented to them, shows that the Department's conclusions were reached and largely set in concrete before the public hearing was ever held. The HHS hearing transcript is remarkable in its lack of dialog, lack of interaction, lack of give-and-take discussion, despite the fact that that was called for in Senator Hawkins' legislation, in the legislative history, and it was clearly indicated that that was the intent of the House-passed companion bill.

The HHS report is remarkable in its lack of responsiveness to the specific points made by Dissatisfied Parents Together. We submitted 29 pages of single-spaced material, and the testimony given at the hearing constituted over 100 pages, and it is largely simply ignored in this report. We find that shocking.

There is the form of consultation without any of the substance.

Second, despite the fact that the HHS report, at least implicitly, admits there is a problem and recommends improvements, the report's recommendations appear largely to be generalities without much substance. There are little or no new commitments in the report for HHS to take specific actions to make these improvements come about, to establish deadlines for action, or to commit specific fund levels to carry out any of these recommendations.

The underlying tone of the report makes clear that HHS will basically continue to react when it is prodded, rather than act in a leadership way to protect the health of our children. The report announces no specific new HHS initiatives to bring about a safer vaccine, to reduce the risk of the current vaccine, or to assure adequate compensation for vaccine-damaged children.

At the same time that HHS is essentially forgoing its proper leadership role, HHS also says, in effect, that no new legislative authority is needed. In effect, HHS is saying that no real change in the pertussis vaccination program is needed. This attitude of HHS is underscored by the material that was provided separately by the Department in response to some of the questions raised by Dissatisfied Parents Together. We only got this yesterday, so we have not had a thorough chance to review it, but I want to point out three or four examples of HHS' unwillingness to take the positive steps necessary to assure better protection of our children's health.

We asked HHS to provide us with copies of the written follow-up procedures that the manufacturers are required to use to investigate a reported adverse reaction. We said, "Please provide a copy of each of the written procedures adopted by Wythe, Lederling, and Connaught in conformance with 21 CFR 211.198." HHS did not give us these materials.

The follow-up procedures, HHS says, are part of the good manufacturing practices which the manufacturers must comply with. Then HHS says:

> It was the intent of the agency, when these regulations were promulgated, to provide manufacturers with as much latitude as possible for efficient review of drug product complaints. Thus, the manufacturers are responsible for development of

their own internal written standard operating procedures in conformance with these requirements. Manufacturers are not required to submit copies of their written procedures for handling oral and written complaints.

We asked later:

Is the FDA aware of any information that these procedures are not being and have not been followed? Please provide that information.

A search of the inspection files for the past five years for the three companies listed in section 6[a] failed to reveal any reported deficiency in the manner in which they are handling complaints.

Thus, what HHS is saying is:

Everything is fine basically, although we won't tell you what the rules are.

We know that the manufacturers are not doing anywhere near adequate followup. The HHS report to Congress itself suggests that more followup on reported reactions is needed.

Our particular case is terribly instructive. Our daughter had a seizure that exceeded 30 minutes on the same day as her third pertussis shot. Since that time she has suffered incredible difficulties which can be described for you and which I have described in the written testimony which is submitted. I do not focus on Julie because she is the only important child in the world. She is my important child, but her case is, I think, instructive for the committee.

Her case was reported to the vaccine manufacturer by the doctor as a DPT reaction. The vaccine manufacturer sent a letter to the doctor requesting minimal information about Julie. The doctor submitted that information in writing, and that information indicated that there had been a 35-minute seizure by a child who previously had not had any difficulties at all.

I checked with the doctor very recently and asked:

Has there ever been any contact by that drug company to find out how Julie is doing, whether she has had any long-term problems, and what was it about her or that vaccine that might have caused the reaction?

No. Not one further contact besides the letter requesting initial information. They have not contacted us. They have not contacted the doctor. There is no real followup system. To proclaim that there is such a system is nonsense.

Yet, FDA, according to their letter to us, is not planning to revise section 211.98 of the regulations, "nor are we considering revisions without a change in the regulations."

It is the same story of inertia, inaction about high-risk children, about recordkeeping. They say, "Yes, we think it is very important that parents have the information—the information about which children may be at particularly high risk and about the contraindication," and so on.

We asked them, "Are you willing to support legislation to require that parents be given this information?"

"No, we will not support legislation. It is not necessary."

Yet, their own report to us tells us that in 1979, when they surveyed this question, less than 50 percent of the parents were getting any information about the risks and benefits of pertussis vaccine, by their own study. That means virtually none of the parents seeking medical care in the private sector received this informa-

tion, because HHS claims that this information is being given in the public sector, which is 50 percent of the market.

We know that parents are not receiving this information. That is clear from the letters pouring in to Dissatisfied Parents Together asking for our parent information booklet so that parents can get the information which they cannot get from the Government and which they are not getting from their doctors. This situation is shocking, and it must not continue.

Dissatisfied Parents Together will make available to parents who request it, for a $3 contribution to cover our costs, this parent information package, until such time as we can embarrass the Government and the medical community into doing the job that is really theirs.

We ask the committee, if HHS is not willing to do it after all this time, if they are not willing to require that it be done, then you must require that it be done.

I am not saying that HHS is populated with evil or insensitive people. I am saying, however, that the Department, of which, by the way, I am a former employee, simply is institutionally incapable of responding to the real world needs for leadership and change on this set of issues.

We have heard an awful lot about numerators and denominators from the Department. What about dead children? What about brain-damaged children?

We heard in the HHS report about one child who died from whooping cough and I sympathize greatly with that family. That family was one that suffered from pertussis disease.

However, we did not hear anything in the HHS report, even though it was raised in the hearings, even though it was submitted in our materials, about children who are dead or brain damaged as a result of the pertussis vaccine. There is a subtle but very pernicious slanting going on in this whole report. Another example of this slanting is that the HHS report says, there is underreporting of the disease. However, it is widely recognized by even some of the strongest proponents of the vaccine that there is underreporting of the vaccine reactions. Yet that is not shown in the HHS reports. Nor is there a commitment to require reporting and recording of the severe reactions that are occurring.

No way will parents believe that the benefits of this vaccine exceed the risks when we have a mandatory reporting system for the disease and no required reporting for the reactions. The system just isn't credible.

Try as hard as I can personally to continue to feel sympathetic to the vaccination program, I think the vaccination program is its own worse enemy. I think it is up to Congress and to parents to help save the system by making it true, by making it complete, by making it honest, and it is not any of those things now.

If you look—and I am sure the committee will look hard—at the answers HHS gave to us and the answers they gave you, the answers they gave to you were all, "Sure, we're in favor of improvements." The answers they gave to us are, "And we're not going to make any." That is what it boils down to.

Now HHS will have sophisticated answers with numerators and denominators, but the concluding is very clear to us. The bottom

line is this: only congressional leadership and legislation can restore our parents 'faith in the system. The credibility of all disease prevention programs stands at risk if inaction and business as usual continue to characterize the Government's response to the real and justifiable concerns of the parents.

The time for congressional action is now. The HHS study says, "We are not going to require changes in the manufacture postmarketing followup. We are not going to require that parent information be provided by the private sector. We are not going to require private sector reporting and recordkeeping requirements. We are not going to support legislation to do that. We are studying high-risk questions and contraindication questions."

Why are they studying it now? This information has been in the published literature for 50 years. Why do they say only the United Kingdom has contraindications that are broader than the United States? Why don't they mention Japan? Why don't they mention the Netherlands? Why don't they mention West Germany, which uses much broader contraindications than we have?

HHS says they are studying the victim compensation program. It has been under study by HHS since 1977. They do not propose to do anything more to compensate children damaged by mandatory vaccination. They propose only more study. How much study is enough?

I think it is pretty clear—it is going to take Congress to make the necessary changes.

We beseech you, not just for the children who have been damaged in the past or who will be damaged in the future by the vaccine, but for the credibility of a genuine disease prevention program, to take the leadership in this.

Now I want to turn my attention—and I appreciate your forbearance during that. It must have come across very harshly. That is not my usual style, but my feeling this morning is so distraught to see the failure of HHS to stand up and say, "We have a real problem. We've got to work on it together. We can no longer do business as usual."

Let me turn now to the question of "victim compensation" versus what we call "victim condemnation", and hopefully present some guiding principles from our standpoint as to how to recognize the difference.

We are committed to the need for good victim compensation legislation. But we are equally committed to oppose bad legislation in this area.

A proposal which promises substantial compensation to meet the needs of these special kids—and they have special kinds of needs—but which is illusory in practice would be a cruel hoax, and any such proposal would be something we would have to oppose.

Even more unfortunate than the cruel hoax-type proposal would be measures which calculatedly are designed to deprive vaccine-damaged children of their rights and remedies under existing law, supposedly in return for some better compensation program.

In our view, the enactment of bad legislation of either type would be far worse than the current situation. We recognize the limits of the tort law system, and our testimony goes into what

those limits are. Our parents have had to suffer with those limits. We are not minimizing those.

In light of those problems with the traditional tort law approach, we have gone on record as supporting alternative compensation. But it has to be recognized that nobody is going to stand up and say, "I'm for a victim condemnation bill." Everybody is going to be for a "victim compensation" bill. The question becomes, how do you know what is what? Which is the genuine program and which is the destructive one masquerading as victim compensation?

The Board of Dissatisfied Parents Together has set forth the following principles which we would ask the committee to consider in evaluating victim compensation program proposals:

One, the program should expressly acknowledge that pertussis vaccines can, and in some cases do, cause serious reactions, including seizures, brain damage, and even death.

Two, the bill must not simply be an effort to sweep the DPT vaccine problem under the rug. Compensating those who are injured by the vaccine and continuing to require virtually all children to take this admittedly dirty vaccine is not an acceptable solution. The bill should contain positive commitments and incentives to reduce the risk of reaction to the current vaccine and promote development of safer vaccines. Parenthetically, that is obviously necessary from a cost-containment strategy as well as from a simple health standpoint.

At a minimum, these requirements and incentives should include requirements for adequate written information to parents on the risks of vaccines and on the contraindications, adequate record-keeping and reporting by doctors and clinics giving the vaccine, more stringent quality control and testing requirements by manufacturers, and more leniency in defining categories of high-risk children who should not be required to receive pertussis vaccine.

Third, and this is quite important, the bill must not restrict in any way a parent's or child's right to sue under existing law. The choice as to whether to sue under existing law or seek some new form of compensation should belong entirely to the parent.

Four, the bill must provide an opportunity for effective compensation for all seriously vaccine-injured individuals regardless of how long ago the injury may have occurred. These folks have not previously had access to an innovative compensation system, and they must have the opportunity to have that access.

Five, the bill should provide a relatively simple, speedy, inexpensive, certain and nonadversarial mechanism for compensation of vaccine-damaged children in order to make it an attractive alternative to parents.

Six, the bill should contain safeguards to assure that the award of the compensation will not depend on proof by the claimant of who the vaccine manufacturer was or on proof of negligence by the doctor or a defect in the vaccine or disproof of all possible alternative explanations for the child's injuries.

Seven, the bill should guarantee a level of compensation which is adequate to enable the damaged child to realize his or her maximum potential and enjoyment of life.

The compensation must not be limited by any arbitrary fixed dollar ceiling, like the $25,000 ceiling in the California legislation.

That ceiling is really shocking when you look at the needs of these kids. Nor should the amount of the compensation be limited by the current availability—or lack thereof—of services to meet the vaccine-injured children's needs.

Eight, the bill must define adequate compensation as being available for the life of the injured person in the case of permanent injury. Also this definition has to include all necessary medical, rehabilitation, special education, therapy, behavioral and emotional counseling, custodial care, residential placement, and any other expenses that are necessary to meet the needs of the child. At a minimum, compensation should also be provided for the victim's loss of earned income and pain and suffering. In the case of a child's death being caused by the vaccine, a substantial death benefit payment should be paid to the parents.

Nine, the persons and institutions deciding vaccine-damage compensation claims under the new optional approach must be completely independent of any governmental or private agency responsible for promoting vaccines or for controlling health care costs.

I can tell the committee now that if you authorize an optional program and then put HHS in charge of deciding who gets compensated, or how much, you will have not one parent choosing that option. When the Secretary is on record as saying, without qualification, that it is child abuse for a parent not to give his child these vaccines, without qualification, we can no longer trust the fate and well-being of our children to HHS. We will not do so. If the committee wants a program that is going to work, it has to put that authority some place else, some place that is independent.

Finally, the financing mechanism of the bill should assure that the payment of compensation awards will not be deferred or reduced because of budget deficits or Government program cutbacks. While the U.S. Treasury should be the ultimate backstop to assure timely and complete payment of compensation, those who have benefited from the vaccination requirement should have primary responsibility to finance the system. The financing system should be designed to recover costs from responsible parties in cases of negligence or defective vaccines to place the responsibility where it belongs.

Assuming these 10 principles are followed, dissatisfied parents together would regard a bill or program which embodies them as a genuine victim compensation program. To the extent that these principles are violated by any bill or proposal, the measure would have to be looked at very carefully to see whether or not it is really a victim condemnation proposal in disguise.

We thank the committee and the Senator for the patience that has been shown here and the attentiveness. We would be pleased to respond to any questions or submit any additional information.

[The prepared statement of Mr. Schwartz follows:]

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TESTIMONY BEFORE THE COMMITTEE ON LABOR AND HUMAN RESOURCES, UNITED STATES SENATE, JULY 22, 1983

Presented by Jeffrey H. Schwartz, on behalf of Dissatisfied Parents Together (DPT)

Members of the Committee, I thank you for the opportunity to appear before you today and present the views of Dissatisfied Parents Together (DPT). I am here today in my capacity both as President of DPT and as the parent of a vaccine-damaged child.

At the outset, I want to thank the Committee for its vigilance and attention in conducting oversight on the nation's vaccination program. I particularly want to express our appreciation to you, Senator Hawkins, for your sponsorship of S. 2950 in the last Congress and for your insistence that the Health and Human Services Department conduct the study and prepare the report that is being reviewed at today's hearing.

To summarize, the testimony which we offer today covers three main points: First, we present a brief synopsis of who and what Dissatisfied Parents Together (DPT) is and what interests we have in the subjects under consideration today; second, we offer our initial comments on the HHS report; third, we would like to discuss the need for so-called "vaccine victim compensation" legislation and the principles that Dissatisfied Parents Together believes should be considered by the Congress in distinguishing potentially useful and humane bills to compensate vaccine-damaged children from positively harmful and cruel bills, which may masquerade as "victim compensation" legislation, but which in reality are "victim condemnation" programs.

I. Dissatisfied Parents Together (DPT)

Dissatisfied Parents Together is a non-profit, tax-exempt foundation, incorporated in the District of Columbia. Its primary purpose is the protection of the health of children, through the promotion of public awareness of the dangers both of pertussis (whooping cough) and of current whole cell pertussis vaccines.

Specifically, DPT is seeking to educate the public with respect to four main needs: (1) the pressing need for a safer pertussis vaccine; (2) the need to reduce the risks of serious adverse reactions to the current whole cell pertussis vaccines by the adoption of certain critical safeguards; (3) the need for an appropriate victim compensation system for those children who are seriously injured by pertussis vaccine (and the corresponding need to avoid what we call "victim condemnation" systems); and (4) the need to develop and use an adequate basic information system (both on pertussis and pertussis vaccine reactions), so that claims that the benefits of the pertussis vaccine exceed the risks can be fairly evaluated.

With the Committee's consent, we would like to submit for inclusion in the record, three items that more fully explain the purposes and concerns of Dissatisfied Parents Together -- a copy of the organization's statement of goals; a copy of the parent information packet which we have developed on pertussis and the pertussis vaccine (including a review letter from Dr. John Freeman of Johns Hopkins University); and a copy of our testimony of March 16, 1983, before the Maryland House of Delegates, Environmental Matters Committee.

These documents underscore several key points about DPT that should be mentioned here:

1. We are not anti-vaccination generally or opposed to child immunization programs. We support properly structured disease prevention programs.

2. We are not focusing on vaccines other than the pertussis part of the DPT vaccine.

3. We are not indifferent to the dangers of pertussis disease. We acknowledge and are concerned about its dangers as much as we are about the dangers of the vaccine. The most serious results of the disease and of a reaction to the vaccine can be similar.

4. We are not advising parents to withhold the pertussis vaccine from their children. We neither oppose, nor recommend, pertussis vaccination at this time. We believe that that is a decision which should be made by informed parents, after thorough consultation with their doctors and after consideration of the specific circumstances of their child's and the community's health.

II. HHS Report on Pertussis and DTP Vaccine

Turning now to the HHS Report which is under discussion today, we would like to make several initial points. Because we have not had the opportunity to thoroughly study the report, our comments should be considered as preliminary, and we would like to submit further comments for the record after a more detailed review has been completed.

Basically, from the standpoint of Dissatisfied Parents Together (DPT), there is good news and there is bad news.

The good news is, in part, that the HHS report in its own indirect way constitutes Departmental acknowledgement that there are significant problems with whole cell pertussis vaccines and with the health care system that administers pertussis vaccines. The other part of the good news is that, in a general way, the HHS report supports the overall goals of Dissatisfied Parents Together (DPT) for addressing these problems:

that is, development and use of a safer vaccine; improved information to physicians and parents; better recordkeeping and reporting on both pertussis disease and serious reactions to the vaccine; more rigorous adherence to the existing contraindications and consideration of more lenient policies for high risk children; and perhaps even a victim compensation plan.

Unfortunately, the bad news is quite bad.

1. Despite the fact that the HHS report at least implictly admits there is a "problem" and recommends "improvements", the report's recommendations appear largely to be generalities without much substance. There are little or no new commitments in the report for HHS to take specific actions, to establish deadlines, or to commit specific fund levels to carry out any of these "recommendations."

2. The underlying tone of the report makes clear that HHS will basically continue to react when prodded, rather than act in a leadership way to protect the health of our children. The report announces no major new HHS initiatives to bring about a safer vaccine, to reduce the risks of the current vaccine, or to assure adequate compensation for vaccine damaged children. At the same time HHS is essentially foregoing its proper leadership role, HHS also says in effect that no new legislative authority or mandate is needed.

3. The HHS report also demonstrates the remarkable "closedness" of the Department's approach to the pertussis vaccine problem. Although a public meeting was admittedly held, there obviously was no "hearing" by HHS at the hearing. A careful comparison of the HHS report with the transcript of the opening statements at the hearing by HHS personnel seems to show that the Department's conclusions were reached and largely set in concrete before the public hearing was ever held. The hearing transcript is remarkable in its lack of dialogue, interaction, and give-and-take discussion of the kind that seemed to us clearly intended by Senator Hawkins' bill and the House-passed bill. The HHS report is remarkable in its lack of responsiveness to the specific points made by Dissatisfied Parents Together. Most of the 29 pages of single-spaced material submitted by DPT and the testimony given at the "hearing" simply is ignored in this HHS report.

I am not saying HHS is populated with evil or insensitive people. I am saying, however, that the Department -- of which, by the way, I am a former employee -- simply is institutionally incapable of responding to the real world needs for leadership and change on this set of issues.

The bottom line is thus clear: only congressional leadership and legislation can restore our parents' faith in the system. The credibility of all disease prevention programs stands at risk, if inaction and business as usual continue to characterize the government's response to the real and justifiable concerns of parents. The time for congressional action is now.

III. Victim Compensation vs. Victim Condemnation: Some Guiding Principles

Turning finally to the subject of "vaccine victim compensation" legislation, DPT is firmly convinced of the need for good legislation to deal with this aspect of the problem. We are equally committed to oppose bad legislation in this area. A proposal which promises substantial compensation to meet the special needs of these quite disabled children, but which is illusory in practice would be one example of a bad bill. Even more unfortunate than the "cruel hoax" type of proposal would be measures which calculatedly are designed to deprive vaccine-damaged children of their rights and remedies under existing law, supposedly "in return for" some allegedly "better" compensation system. In our view, the enactment of bad legislation of either type would be far worse than the current situation.

Surely anyone familiar with the tort law system -- as many of our families have had to become -- knows that it has very severe drawbacks and limitations as an instrument of justice. Among these shortcomings are the following:

* the high costs of filing, expert witness and other "fees" (not counting lawyers' fees) to bring a lawsuit ($5,000 - $60,000);

* the "technical" legal barriers to full consideration of the merits of a compensation claim (such as statutes of limitations, technical rules of evidence, etc.);

* the inability of many parents to discover the manufacturer of the vaccine given to their child;

* the difficult standard of proof required by courts to prove that the child's injuries were caused by the vaccine (and could not have resulted from some other cause), and that the vaccine was defective or unreasonably dangerous or the doctor was negligent in giving it;

* the great delay in resolving lawsuits (often more than 5 years); and

* the potential cost of attorneys' fees in a successful case (perhaps as much as 30% - 50% of a settlement or appealed verdict).

In light of these "problems" with the traditional tort law approach to compensation of vaccine-damaged children, Dissatisfied Parents Together has gone on record as supporting an alternative approach to vaccine victim compensation. A good victim compensation bill could be a Godsend for the children (and their families) all across the country who are suffering pertussis vaccine related injury. A bad bill, however, could be a disaster for these children. It could be the final insult from the "medical-legal system" that has already inflicted such terrible damage. A bad bill could condemn these children forever to a life of insufficiency, isolation, and invisibility.

That is why we see the crucial choice confronting Congress as a decision between genuine "victim compensation" and effective "victim condemnation." Of course, no one will stand up to oppose compensation of vaccine-damaged children in principle or to favor "condemnation" of the victims. So, how can Congress know which bills provide for genuine "compensation" and which proposals may be "victim condemnation" programs masquerading as "compensation" programs?

The remainder of our testimony is directed to providing some initial answers to this question. The Board of Dissatisfied Parents Together has set forth the following principles for defining a genuine vaccine victim compensation bill:

1. The bill should expressly acknowledge that pertussis vaccines can, and in some instances do, cause serious reactions, including seizures, brain damage, even death.

2. The bill must not simply be an effort to sweep the DPT-vaccine problem under the rug. Compensating those who are injured by the vaccine and continuing to require virtually all children to take this admittedly "dirty" vaccine is not an acceptable solution. The bill should contain positive commitments and incentives to reduce the risks of reactions to the current vaccine and to promote development of safer vaccines. As a minimum these commitments and incentives should include: requirements for adequate written information to parents on the risks of the vaccine and on the contraindications to the vaccine; adequate recordkeeping and reporting by doctors and clinics giving the vaccine; more stringent quality control and testing requirements by manufacturers; and more leniency in defining categories of high risk children who should not be required to receive the vaccine.

3. The bill must not restrict in any way a parent's (or child's) right to sue under existing law. The choice as to whether to sue under existing law or to seek this new form of compensation should belong entirely to the parents.

4. The bill must provide an opportunity for effective compensation for all seriously vaccine-injured individuals, regardless of how long ago the injury may have occurred.

5. The bill should provide a relatively simple, speedy, inexpensive, non-adversarial mechanism for compensation of vaccine-damaged children.

6. The bill should contain safeguards to assure that the award of compensation will not depend on proof by the claimant of who the vaccine manufacturer was; on proof of negligence by the doctor or defect in the vaccine; or disproof of all possible alternative explanations for the child's injuries.

7. The bill should guarantee a level of compensation which is adequate to enable the damaged child to realize his or her maximum potential and enjoyment of life. Allowable compensation must not be limited by any arbitrary fixed dollar ceiling or by the current availability of services (or lack thereof) to meet the vaccine-injured children's needs.

8. The bill must define allowable compensation as being available for the life of the injured person in the case of permanent injuries, and as covering all necessary medical, rehabilitation, special education, therapy, behavioral and emotional counseling, custodial care, residential placement and other necessary expenses. At a minimum compensation should also be provided for the victim's loss of earned income and pain and suffering; and in the case of a child's death being caused by the vaccine, a substantial death benefit payment should be provided for the parents.

9. The persons and institutions deciding vaccine-damage compensation claims under the new optional approach must be completely independent of any governmental or private agency responsible for promoting vaccines or for controlling health care costs.

10. The financing mechanism of the bill should assure that the payment of compensation awards will not be deferred or reduced, because of budget deficits or government program "cut-backs." While the Treasury should be the ultimate back-stop to assure timely and complete payment of compensation, those who have benefitted from the vaccination requirements should have primary responsibility to finance the system. The financing system should be designed to recover costs from responsible parties in any cases of vaccine-injury due to negligence in the manufacture or administration of the vaccine or to defect in the vaccine itself.

Assuming these ten principles are followed, Dissatisfied Parents Together would regard the bill which embodies them as a genuine "victim compensation" bill. To the extent that these principles are violated by any bill or proposal, the measure would have to be regarded more as a victim condemnation bill.

We again thank the Committee for the opportunity to appear and would be pleased to respond to any questions.

Senator HAWKINS. Thank you, Jeff. We will get back to you with some questions.

Dr. Smith, we would now like to hear a summary of your remarks, please.

STATEMENT OF MARTIN H. SMITH, M.D., REPRESENTING THE AMERICAN ACADEMY OF PEDIATRICS

Dr. SMITH. Thank you, Madam Chairman.

You have a full copy of our testimony, and I would ask that it be a part of the record. I will try to be brief by summarizing that testimony.

I am Dr. Martin H. Smith, here today representing the American Academy of Pediatrics. On behalf of the Academy, I want to commend you for your leadership and support of the childhood immunization program. We thank you for the opportunity to present testimony this morning on sensitive issues which could seriously impact the future of this vital program.

The United States should stand proud that at the time of school entry more than 95 percent of our children are fully immunized. However, lest we become complacent in our successes, consider for a moment the peak occurrence and death rates from childhood diseases before the vaccine era.

So that you can readily see these, we have displayed them on the chart here (indicating chart).

[The chart referred to follows:]

COMPARISON OF MAXIMUM AND CURRENT MORBIDITY AND MORTALITY DUE TO VACCINE-PREVENTABLE DISEASES IN THE UNITED STATES

Disease	Morbidity: Max No. Cases (Yr)	Morbidity: 1981 Cases	Mortality: Max No. Deaths (Yr)	Mortality: Deaths 1979
DIPHTHERIA	206,939 (1921)	5	15,000 (1921)	1
MEASLES	894,134 (1941)	3,124	6,989 (1934)	6
MUMPS*	152,209 (1963)	4,941	55 (1952)	2
PERTUSSIS	265,269 (1934)	1,248	7,518 (1934)	6
POLIO (PARALYTIC)	21,269 (1952)	6	3,145 (1952)	4
RUBELLA**	57,686 (1969)	2,077	53 (1964)	1
TETANUS***	601 (1948)	72	1,253 (1933)	30

*FIRST REPORTABLE IN 1968
**FIRST REPORTABLE IN 1966
***FIRST REPORTABLE IN 1947

Dr. SMITH. With the peak years of occurrence of each one of the common childhood diseases displayed and contrasted with the current status of those diseases, the contrast and the death rate in the peak years and the contrast today should give a clear demonstration of the risk-benefit ratio that goes on with the conduction of the immunization programs.

I would call attention to one misleading, benign appearance in the rubella statistics. Actually, in 1964, which was the peak year of occurrence of rubella, the death rate was not high because it is a relatively benign disease. However, in 1964 there were 12 million cases of rubella. This resulted in 11,000 fetal deaths. Further, it resulted in 20,000 babies being born with the rubella syndrome. This includes severe defects of the brain, eyes, and the heart.

It has been estimated that the economic impact of that rubella epidemic was $1.5 million.

If we ceased immunizations today, our larger population today would multiply these figures proportionately. Yet, despite the enviable track record of our Nation's childhood immunization programs, a few children each year will suffer adversely from the vaccines themselves. We can expect a case of paralytic polio to result out of each 5 million doses of polio vaccine; a serious, permanent, neurological injury to result from every 300,000 doses of DPT; and, in extremely rare cases, encephalitis or nerve deafness from the MMR vaccine.

Thus, with the doses administered each year of these products, there will be approximately 2 cases of paralytic polio and at least 50 permanent neurological injuries that result. This is a year-in and year-out annual total from our immunization program itself. These occur through no fault of the provider or the producer of the vaccine.

The Academy is the strongest advocate for children in this country. On behalf of children, we have strongly advocated our present immunization system. In their behalf, we have supported the legal mandating of full immunizations for all school age children in all 50 States. Without these legal requirements, we could never have reached and could not maintain the 95-plus percentage immunization level that gives us the present low incidence of preventable childhood diseases. We require immunization of school age children for the public good, but when the small percentage of serious injuries inevitably occur, we abandon those children to the slow, tedious, and uncertain court process for compensation of their injuries and care for the rest of their lives.

Since 1977 it has been the Academy's stated policy that children who are injured in the process of complying with mandated immunizations should have adequate compensation provided by the public without the necessity of pursuing their claims in the court. This is not a new idea. Some form of such process exists, and has existed for years, in many West European countries and in Japan.

We are not advocating this step as a service to physicians or to the vaccine producers, but as simple justice for the children who are our patients. At present, parents must try to prove fault in the production of the vaccine or in the administration of the vaccine to win injury compensation.

Vaccine production is under the supervision of the Bureau of Biologics of the Food and Drug Administration. It is unlikely that faulty vaccine can be proven. Vaccines administered totally without fault can and do cause serious injury. So the only avenue for the injured to seek compensation is to claim failure of informed consent. In at least 50 percent of the cases the vaccine is administered in a public clinic where a written and informed consent is required and executed. Therefore, in these situations simple justice is difficult to obtain under the tort process.

Our next concern in advocating a vaccine compensation system is the assurance of a certain and competitive vaccine supply, along with allowing for incentives for research into new vaccine and an improved qualty of existing vaccines.

Over the past several years, with the rapidly increasing burden of liability risk, the numbers of producers of vaccines in this country have rapidly decreased. We now have only one producer for the polio vaccine; only one producer for the measles, German measles, and mumps vaccine; and three producers for the DTP vaccine. If there is any further elimination of producers, the supply of some or all vaccines for the entire country could vanish.

During 1982 there was an increase in the cost of vaccines averaging 30 percent. Already in 1983 there have been further sharp increases in cost. We do not know what part of these price increases is due to the producers' liability costs. We do know that those costs are considerable and that they are bound to be reflected in the present cost of the vaccines. We must assume that as long as there are no competitive incentives, there will not necessarily be limits to the increases.

Madam Chairman, you have asked for the Academy's views concerning proposed legislation to be considered by this committee that would provide for a Federal compensation program for vaccine-related injuries in childhood immunization programs. It is our considered opinion that the problems discussed today will only continue to increase unless and until Federal legislation establishing a program that provides an attractive alternative to the existing tort system is enacted and properly implemented.

Thus, the Academy strongly recommends establishment by law of a Federal "no-fault" system of compensation, based on existing medical evidence, that would cover those who suffer vaccine-related injuries resulting from childhood vaccination programs. We believe that the Federal compensation system should be an option to the existing tort system, but that it not be the exclusive remedy available to children. An election to pursue a Federal compensation program should, however, be binding on a child and on his or her representative in most instances.

We recommend that under the Federal program compensation be available for major adverse reactions which manifest themselves within certain time periods after administration of a childhood vaccine. These reactions and time periods should be specified in the legislation itself, for administrative ease, but should be subject to modification by rulemaking, and our recommendations to the committee will include these specifications.

Further, we recommend that the approximate costs of the compensation program should be raised by revenues generated by a

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vaccine dosage surcharge calculated by the Secretary of Health and Human Services.

Thus, under our proposal compensation would be available whether or not a person could prove negligence in a court of law. Causation would be established simply by demonstrating the circumstances surrounding a child's injury are consistent with specified reactions and time periods.

The principal issue would be the amount of compensation to be awarded, which we believe should be determined by a special master appointed by a Federal district judge.

We recommend that the program itself should be supervised by an expert committee within the Department of Health and Human Services.

Madam Chairman, as you know, over the past 4 months the Academy has had extensive and productive discussions with members of Dissatisfied Parents Together, the DPT group, concerning the specifics of legislation related to victim compensation. The goal of the Academy is to present for the committee's consideration proposed legislation with which both the Academy and DPT agree. We have been most impressed by the skill and knowledge of the parents, and, frankly, we have learned a great deal from them. Our progress to date, in our view, has been facilitated by a strong mutual desire by both parties to accomplish simple justice for children. That is our common goal, and it is the goal which we recognize that you share.

We would be happy to answer any questions that we can.

[The prepared statement of Dr. Smith follows:]

American Academy of Pediatrics

TESTIMONY

BEFORE THE

UNITED STATES SENATE
COMMITTEE ON LABOR AND HUMAN RESOURCES

ON

COMPENSATION FOR VACCINE-RELATED INJURIES

PRESENTED BY

MARTIN H. SMITH, M.D., F.A.A.P.

JULY 22, 1983

Division of Government Liaison
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Madame Chairman, I am Dr. Martin H. Smith, here today representing the American Academy of Pediatrics. On behalf of the Academy, I commend you for your leadership and support of the childhood immunization program, and thank you for the opportunity to present testimony this morning on sensitive issues which could seriously impact the future of this vital program.

43/ This United States should stand proud that at the time of school entry more than 95 percent of our children are fully immunized. They enjoy substantial freedom from the ravages of once common communicable infectious diseases which limited life expectancy and left tens of thousands disabled in their wake. This distinguished record of accomplishment can be attributed to a strong commitment by the federal government, state governments (all 50 states now require proof of vaccination before admission to school), the medical community and industry.

Lest we become complacent in our successes, however, consider for a moment the peak occurrence and death rates from childhood diseases before the vaccine era. Bear in mind that during this time the population of the country was much smaller. If we ceased immunizations today, our larger population would multiply these figures proportionately.

COMPARISON OF MAXIMUM AND CURRENT MORBIDITY AND MORTALITY
DUE TO VACCINE-PREVENTABLE DISEASES IN THE UNITED STATES

DISEASE	MORBIDITY		MORTALITY	
	MAX NO. CASES (YR)	1981 CASES	MAX NO. DEATHS (YR)	DEATHS 1979
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TETANUS***	601 (1948)	72	1,253 (1933)	30

* FIRST REPORTABLE IN 1968
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46A Yet despite the enviable track record of our nation's childhood immunization program, a few children each year will suffer adversely. We can expect a case of paralytic polio to result out of each five million doses of polio vaccine, a serious, permanent neurological injury to result from every 300,000 doses of DTP, and in extremely rare cases, an encephalitis or nerve deafness from MMR. Thus, with the doses administered each year of these products, there will be

approximately two cases of paralytic polio and at least 50 permanent neurological injuries that result -- and these occur through no fault of the provider or the producer of the vaccine. This is an annual year-in and year-out toll that is inevitable in maintaining a fully immunized population. It should be noted that while these examples are the most serious and major injuries, there are also other injuries that occur.

We must accept the fact that in individual instances there have been, and will continue to be for the foreseeable future, tragedies that result from the use of the vaccines currently available. We would hope and expect that continued research and developments of improved vaccines will remove some, if not all, of these risks. But that day is not at hand. Until these risks can be removed, the greatest good for the entire population will have to be served by the continuation of the vigorous immunization program now in effect.

Society is the beneficiary of our compulsory immunization laws. Yet when the small percentage of serious injuries inevitably occurs, we abandon those children to the slow, tedious and uncertain tort process for appropriate compensation. Under the present system parents are forced to re-visit over an extended period of time the tragedy that has occurred with their child, and relive a very difficult, emotional crisis.

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Since 1977 it has been the Academy's stated policy that children who are injured in the process of complying with mandated immunizations should have adequate compensation provided by the public without the necessity of pursuing their claims in court. The tort process, as aforementioned, is slow, expensive, and uncertain, while the needs of the children are expensive and immediate. This is not a new idea. Some form of such process exists, and has existed for years, in many West European countries and in Japan.

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We are not advocating this step as a service to physicians or to the vaccine producers -- but as simple justice for the children who are our patients. At present, parents must try to prove fault in the production of the vaccine or in the administration of the vaccine to win injury compensation. Vaccine production is under the supervision of the bureau of biologics of the Food and Drug Administration, and it is unlikely that faulty vaccine can be proven. Vaccines administered totally without fault can and do cause serious injury, however, so the only avenue for the injured to seek compensation is to claim failure of informed consent. In at least 50 percent of the cases the vaccine is administered in a public clinic where a written and informed consent is required and executed. Therefore, in these situations simple justice is difficult to obtain under the tort process.

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Our next concern in advocating a vaccine compensation system is the assurance of a certain and competitive vaccine supply, along with allowing for incentives for research into new vaccine and an improved quality of existing vaccines. Over the past several years, with the rapidly increasing burden of liability risk, the numbers of producers of vaccines in this country have rapidly decreased. We now have only one producer for the polio vaccine, only one producer for the measles, german measles, and mumps vaccine, and three producers of the DTP vaccine. Since one producer is the producer of several of these vaccines, the pre-

vention of the seven diseases in the usual school-entry requirements is totally in the hands of only three vaccine producers. If there is any further elimination of producers, the supply of some or all vaccines for the entire country could vanish. Not only can this supply be interrupted by a change of plans by one or more of the companies, but we are vulnerable as well through natural circumstances, such as a plant fire, to interruption of supply.

During 1982 there was an increase in the cost of vaccines averaging 30 percent. Already in 1983 there have been further sharp increases in cost. We do not know what part of these price increases is due to the producers' liability costs. We do know that those costs are considerable and that they are bound to be reflected in the present cost of the vaccines. We must assume that as long as there are no competitive incentives, there will not necessarily be limits to the increases.

There are opportunies before us for the development of valuable new vaccines, and there is need for modification of existing vaccines. But there is very little incentive for undertaking this research in the present severe liability atmosphere.

Madame Chairman, you have asked for the Academy's views concerning proposed legislation to be considered by this committee that would provide for a federal compensation program for vaccine-related injuries in childhood immunization programs. It is our considered opinion that the problems discussed today will only continue to increase unless and until federal legislation establishing a program that provides an attractive alternative to the existing tort system is enacted and properly implemented. Thus, the Academy strongly recommends establishment by law of a federal "no-fault" system of compensation, based on existing medical evidence, that would cover those who suffer vaccine-related injuries resulting from childhood vaccination programs, whether or not negligence or fault existed. We believe that the federal compensation system should be an option to the existing tort system, but that it not be the exclusive remedy available to children. An election to pursue a federal compensation program should, however, be binding on a child and on his or her representative in most instances. We recommend that under the federal program, compensation be available for major adverse reactions which manifest themselves within certain time periods after administration of a childhood vaccine. These reactions and time periods should be specified in the legislation itself, for administrative ease, but should be subject to modification by rule making, and our recommendations to the committee will include these specifications. Further, we recommend that the approximate costs of the compensation program should be raised by revenues generated by a vaccine dosage surcharge calculated by the Secretary of Health and Human Services.

Thus, under our proposal questions of negligence and causation would not be at issue if an election were made to pursue the federal compensation program. Rather, the principal issue would be the amount of compensation to be awarded, which we believe should be determined by a special master appointed by a federal district judge. We recommend that the program itself should be supervised by an expert committee within the Department of Health and Human Services.

Madame Chairman, as you know, over the past four months the Academy has had extensive and productive discussions with members of Dissatisfied Parents Together (DPT) concerning the specifics of legislation related to victim compensation. The goal of the Academy is to present for the committee's consideration proposed legislation with which both the Academy and the DPT agree. We have been most impressed by the skill and knowledge of the parents, and frankly we have learned a great deal from them. Our progress to date, in our view, has been facilitated by a strong mutual desire by both parties to accomplish simple justice for children. That is our common goal, and it is a goal which we recognize you share.

Senator HAWKINS. Thank you so much, Dr. Smith.

In your opinion, in the absence of legislation, how do you see the impact of vaccine liability 5 years down the road?

Dr. SMITH. We are very concerned, without some form of compensation legislation, that in less than 5 years we would reach a crisis situation, either in the supply of vaccine or in the cost of vaccine that would make it unobtainable for a large segment of our population. We are very afraid that the increasing liability situation that we have alluded to is going to lead to that crisis. We cannot afford that crisis. We have to immunize every year, year-in and year-out, 3 million children or we will begin to have serious gaps in our protected population.

Senator HAWKINS. In your opinion, is a national system of compensation preferable to a State system?

Dr. SMITH. We have discussed this aspect of our proposal over and over, and we are convinced that a State system cannot meet the needs; that there are innumerable problems that would exist in the States trying to carry on this program. There are varying degrees of interest in the States, as well as varying capabilities in the States to carry on such a program.

Immunizations are administered across State lines, and in that sort of instance who has jurisdiction? Whose responsibility is it? Vaccines are produced centrally in one location in the country generally. Distribution is across State lines.

We believe there are insurmountable problems in a State system and that it can only be handled on a national basis.

Senator HAWKINS. What about the cost of such a system?

Dr. SMITH. Pardon?

Senator HAWKINS. What about the cost of such a system?

Dr. SMITH. The Academy has been concerned, as we all will be, about the cost of the system. We have commissioned a study by health economists at the University of Illinois to develop a preliminary cost estimate for us. We would be happy to share that report with the committee.

However, the figures that we have and the estimates that can be made of the cost of the system are only a partial answer. We all know that there is a very considerable cost going on right now in the sort of system that we have; that those present costs are buried in the cost of the vaccine.

We have not been able to obtain at all, and we have tried repeatedly, the cost of the present system. Unless we have those figures and can subtract those from the estimates that we have of the proposed system, we cannot say whether there is any new cost at all involved. We think that the new cost could be minimal.

Senator HAWKINS. How about the cost to the Federal Government? It purchases about 50 percent of the total amount of vaccine.

Dr. SMITH. That is very true. The Federal Government does purchase approximately 50 percent. The Federal Government would be paying 50 percent of the total surcharge. However, I would again submit that the Federal Government is presently paying a considerable cost in the present system, whether it is recognized as such or not.

Senator HAWKINS. But in the end, the public really bears the cost?

Dr. SMITH. Finally, of course, always.

Senator HAWKINS. Whether we have surcharge, as you suggested, or another system?

Dr. SMITH. That is right.

Senator HAWKINS. Do you know anything about experience in other countries which have a compensation system? Has your Academy looked into that?

Dr. SMITH. We do know, and we have received from the World Health Organization copies of the legislation as it exists in Great Britain, France, Germany, Japan. The programs are in effect in most of the Western European countries and in Japan. They are evidently satisfied with the performance of the program and feel that it is doing the best job for this particular need. It has been in existence for several years at those locations and is continuing there.

Senator HAWKINS. What do you recommend where death occurs as the result of pertussis?

Dr. SMITH. We feel that all of the settlements that should be incorporated into the compensation system should be realistic settlements and should be settlements that fit the circumstances. If that is not the case, if we do not provide realistic settlements, then we will have created a system that nobody will utilize, certainly, if this is an option. If it is going to be an option, then we must provide reasonable settlements.

In the case of death, certainly, we think that there should be a reasonable lump sum settlement, once it is definitely associated with the vaccine.

Senator HAWKINS. In your opinion, why is there such resistance from private physicians to giving the parent the information necessary prior to the child having a shot?

Dr. SMITH. I am convinced that the resistance is rapidly decreasing.

Senator HAWKINS. As we speak?

Dr. SMITH. Well, no, not necessarily, but a few years ago, at one of the meetings of the Academy of Pediatrics, the question was asked of the audience, "Do you provide information on vaccines and their reactions to parents before they are given vaccines?" Only a very few hands went up in the room. In the past year the same question was asked. About a third did respond that they are providing information now. I think that the numbers are increasing very rapidly and that this is one of the things that can be spelled out in the legislation and is justifiable to be incorporated in it.

Senator HAWKINS. Thank you so much, Dr. Smith. You have been most helpful to us.

I would like to turn to you for some questions.

Could you give me some specific examples to justify your charge that HHS did not really listen or respond to the parents at the public hearing that you referred to which the Department held?

Mr. SCHWARTZ. I think there are a number of examples in the oral testimony I gave that went beyond my written testimony.

Clearly, one of the things that was the most shockingly sad to me was that the HHS report—I mentioned this—talks about a death of a child as a result of the pertussis disease but it does not mention

that at the hearing a mother testified about her child who died on the same day as a result of a vaccine and reaction. It does not mention that. The HHS report does not have that kind of balance.

In our proposal, in our 29 pages of material, we submitted a lengthy, detailed documentation from the literature, including citations from eminent authorities in the Academy to the effect that there is underreporting of the vaccine reactions.

There is the statement in the report that there is underreporting of the disease. There is not the comparable statement, "Yes, and there is underreporting of the reactions."

Over and over again there is this lack of balance. It is very disturbing to us to see that.

Perhaps most disturbing is that in the course of the testimony—and this did not come exclusively from our group—there were a number of people who challenged, both the claimed efficacy of the current vaccine and the adequacy of the current studies that quantify risk of adverse reactions. These comments, data, and analysis suggest that the reaction rates may be much higher than officially acknowledged because of deficiencies in the basic studies. The California study, for instance, excluded children who had had prior reactions to shots from the studies, and thereby effectively understated the real world reaction rates. The same study excluded certain children who had reactions outside the 48-hour monitoring period of the study, even though it is recognized that reactions may occur way beyond 48 hours.

Those points were made in the course of the hearing. There is no reference to these points in the HHS report. There is no response to the parents' critiques. They were just dismissed by silence.

Senator HAWKINS. You said that you received the answers to your questions——

Mr. SCHWARTZ. Not all of them.

Senator HAWKINS [continuing]. Yesterday?

Mr. SCHWARTZ. Yesterday, yes.

Senator HAWKINS. But you still haven't gotten all of the answers?

Mr. SCHWARTZ. That is right. I must confess we tried to pose some tough questions, and I suppose a couple of them required the General Counsel's Office to look at HHS authority.

I would have liked to believe that in their General Counsel's Office they would have long ago looked at their authority to do the things we have proposed. But we are assured that we will get the answers within the next week. We will be pleased to share them with the committee.

Senator HAWKINS. We would like you to do that, if you will, please.

Your testimony does not discussion the meetings which I understand have been held between representatives of your parents group and the Academy of Pediatrics. Could you tell us, from the standpoint of Dissatisfied Parents Together where these meetings stand at this point?

Mr. SCHWARTZ. Yes, Senator. I should say at the outset I appreciate the kind words from Dr. Smith about our group. We have tried hard to be responsible and to listen as well as talk.

Frankly, when we saw the Academy's first draft, its the March 11 document, we felt deeply upset and concerned because that document had a number of points in it that violated the 10 principles for good victim compensation legislation that we have laid down. We were very deeply disturbed about it.

However, we did contact the Academy and indicate our set of concerns and we were relatively pleased by the Academy's responsiveness. We found out that that March 11 draft was not necessarily the Academy's final word, but was an attempt on the Academy's part to initiate active consideration of these issues.

The result is that we started a series of meetings with the Academy, and those meetings continue. We have made a lot of progess in terms of identifying areas of common agreement. There are still several important areas where no agreement has been reached and issues are yet to be resolved.

We will be happy to advise the committee as to our continuing progress. It is important for the committee to be aware, however, that what is happening is that the Dissatisfied Parents Together negotiating team is meeting with a negotiating team for the Academy. Neither group has signed off on any of the preliminary discussions at this point. That is going to take both resolution of the remaining issues at the negotiating level and then discussion with the groups and decision by each as to whether or not they can live with the emerging agreement.

Senator HAWKINS. But you are making progress, as I understand it?

Mr. SCHWARTZ. The short answer is, yes, we are making progress.

Senator HAWKINS. You will keep us informed?

Mr. SCHWARTZ. Yes, we will.

Senator HAWKINS. Your testimony refers to victim condemnation legislation. Could you provide the committee with any examples of bills or proposals which you regard as being the type of legislation that you would prefer and explain why you think it is victim condemnation legislation?

Mr. SCHWARTZ. There are two that come to mind right away. One of them is the California legislation that theoretically is a victim compensation provision, but it establishes a total compensation ceiling of $25,000. It theoretically exempts physicians from any liability, no matter whether they gave the vaccine in the face of obvious contraindication, and it has a number of other provisions that we regard as totally unsuitable.

Frankly, looking at the March 11 draft of the Academy—and I do not mean anything about the motives here but only the content—we would have regarded parts of that draft, and particularly the part that would preempted parents' rights to sue or made the compensation program the exclusive remedy—we would have regarded that provision alone sufficient to make it a victim condemnation proposal.

However, I believe that Dr. Martin Smith personally is deeply committed to simple justice for children, and I am belatedly and reluctantly coming to the conclusion that maybe the Academy is, too. It remains to be seen, whether or not we can reach agreement. However, I certainly believe Martin Smith's good faith. I believe that the Academy wants—I do not think these people went into

this particular form of medicine merely to make money. There are other ways to make more money in medicine. I think that they do care about children. I think some kind of agreement may be possible here and I hope we will be able to help the committee in that regard.

Dr. SMITH. Madam Chairman, if I may, let me clarify one point.

Mr. Schwartz has alluded to our proposal for legislation that was submitted on March 11, and the CDC has referred to it. This was simply a first draft. There had to be some starting point. We regarded it as a starting point, something that we would all have to work at and mold before it reached final resolution.

We acknowledge that our March 11 draft proposal has been changed considerably. We have debated a great many points with the DPT group. We have reached a great many important points of agreement. There will be other points that we will have to tackle, but we do not have at this time any major disagreements.

Mr. SCHWARTZ. Well, we have at least some areas of nonagreement that we regard as important. Hopefully, they are reconcilable. However, from our standpoint at least, there are remaining unresolved questions of great importance.

Senator HAWKINS. Those are the areas of discussion that you could continue.

Mr. SCHWARTZ. We are continuing.

Senator HAWKINS. And working very closely with my staff, also. I appreciate the comity that we have here.

Jeff, you referred to a wide range of services that may be necessary, in your mind, to assist vaccine-damaged children. Could you tell the committee how these children differ from other disabled youngsters?

Mr. SCHWARTZ. The main problem that the committee needs to understand, and why the compensation system may for an individual child be quite costly, and why litigation is quite costly, is that these kids, the severely damaged ones, do not have simply one kind of problem. They have massive numbers of problems.

They may have uncontrolled seizures which nonethess require frequent medication. They may have major motor problems and be unable to provide even the most basic care for themselves. They may have intellectual problems and speech and language problems. They may have problems that are emotional in nature in which the brain damage that has resulted has caused the behavioral inhibitors to be reduced and cause some bizarre behavior or lack of emotional control. It may cause outbursts of rage, a number of other problems.

By virtue of all these other problems, they may be subject to more frequent injury, accidents. They may require constant care. They may have needs that are just immense and that require a range of services that can be quite expensive.

That is why you see huge verdicts and settlements in these kinds of cases where they are reached.

Senator HAWKINS. Given the testimony that Dr. Smith gave us where these cases would come to a tribunal that would resolve this, wouldn't the cost of the compensation program be quite expensive?

Mr. SCHWARTZ. I think the costs could be seen as high when you look at them in the abstract. But I agree with Dr. Smith, you also

have to look at what are the costs of not having a victim compensation program.

If you look at the cost to the Government alone of one settlement as a result of maladministration of the vaccine in Georgia, we are talking about over $1 million for that one case alone under the current tort law system.

The current tort system also has to pay high transaction costs.

What is most important to understand is right now there are costs of the vaccine injuries, damages, but they are being sustained, by and large, by the injured children and families themselves. That is not simple justice.

I think it is a tremendous contribution by the Academy to introduce the standard of simple justice. If we are going to ask these kids, require these kids to bear this risk, then decency, humanity, fairness, caring requires that we take care of the kids who are injured. I mean really take care of them, not with some phony appropriate measure that gives them enough to get by and be invisible, but something that really says, "We care about you, just as we care about soldiers whom we drafted and who are injured in the service of their country." We can at least treat our injured children with decency and respect.

Senator HAWKINS. Surely.

In the large amounts of money that have been awarded through court costs, not all of that goes to the family.

Mr. SCHWARTZ. For certain.

Senator HAWKINS. A tremendous amount goes to the lawyers involved and the whole system.

Mr. SCHWARTZ. Indeed, just bringing a case, apart from the lawyers' fees, can cost a family anywhere from $5,000 to $60,000 for witness fees and filing costs, and so on. That is not fair to the families. It is not good for the economy. It is not right. If we can come up with a system that is simpler and speedier and fairer and cheaper, fine, we are for it. We think we may be able to do that.

Senator HAWKINS. Why does DPT keep emphasizing issues like recordkeeping and reporting, which a lot of people think is just more redtape? I have heard that a lot since we started this investigation in 1982.

Mr. SCHWARTZ. It is easy to feel that way. Recordkeeping and reporting sound like more bureaucratic nonsense and paper shuffling.

However, if you look at it from the standpoint of the parents, there are two important reasons why these things are so important to us. One is, if you are going to have a victim compensation system and the parent is going to demonstrate that his child was injured by the vaccine, how can he prove it but by the medical records that the doctor keeps? When he or she tells the doctor this is what happened, if the doctor refuses to write it down and refuses to report it, if the doctor refuses to provide that information to the authorities, then the parent has no way to demonstrate what happened to the child.

In terms of protecting the child's future health, it is only decent for that child's medical record to contain the realities of his health situation. That is part one.

Part two relates to the story told over and over again by HHS about pertussis vaccine HHS' story is that the benefits exceed the risks. Well, nobody is going to believe that the benefits exceed the risks if you do not have an adequate recordkeeping and reporting system for keeping track of vaccine reactions.

Right now doctors are not required to keep the names and lot numbers of the manufacturers and vaccines that are used. They are not required to report serious adverse reactions, and so on.

I cannot believe that the cost of this recordkeeping and reporting would be so huge. Mandatory reporting is required for the disease, and it is not that expensive. I also can't believe something else that HHS says, which is in their letter to us. HHS says, "We do not think necessarily that requiring recordkeeping and reporting by the doctors will result in any improved recordkeeping and reporting." If it is in the law, we believe the doctors will comply.

Senator HAWKINS. That was one of the problems in this whole undertaking of the hearing—the inadequate amount of data that we could find because of the inadequate amount of recordkeeping. We are talking about children's health and bodies, as you know.

If parents are interested in getting a copy of the parent information package that you told them they could get for $3, could you tell us where parents could write to get that information?

Mr. SCHWARTZ. Yes; we have made the information available to the committee, the parent information packet, but parents can write to: DPT, Box 563, 1377 K Street NW., Washington, D.C., 20005, and request the parent information packet and we will send it. They need to send $3 to cover the mailing and printing costs.

Frankly, we would love to go out of business——

Senator HAWKINS. I know it.

Mr. SCHWARTZ [continuing]. Passing out this information. We would love to.

The information is good information. We have had it reviewed by a doctor at Johns Hopkins who said that it is fair and useful. We hope that the doctors and the Congress and HHS will take us out of the business by making sure that the job of fully informing parents gets done by those who ought to be doing it.

Senator HAWKINS. We have a copy of it. It is very good. We would like all parents to have a copy of it. We appreciate your caring enough to make that available to all parents.

Thank you, Jeff and Dr. Smith. We look forward to working with you in the future and solving this problem.

Our next panel, and final panel, will be Mrs. Wendy Scholl, a constituent of mine from Palm Harbor, Fla., who has spent the past 5 years pursuing legal remedies in an attempt to receive some financial assistance to help her care for her child, who suffered an apparent adverse reaction to measles vaccine, and Mr. Robert Kaufman, a trial attorney from Gaylord, Mich., who is familiar with the process of seeking compensation for vaccine-related injuries through our current tort system.

Wendy, I understand you have a statement you would like submitted for the record. We would be happy to include that.

You believe your daughter Stacy suffered an adverse reaction to a measles vaccination, and you filed a tort claim on her behalf.

Could you tell us how this has affected you and your family's lives for the past few years?

STATEMENT OF WENDY SCHOLL, PALM HARBOR, FLA.

Mrs. SCHOLL. First, I would like to say that I believe it to be true because we were one of the lucky victims what I mean by that is my daughter was diagnosed as having post vaccinal encephalitis. There was not the indifference originally to our case that there has been with many other parents or victims in acknowledging that this does happen.

Senator HAWKINS. You say you are one of the lucky parents because your child was diagnosed as having a reaction from the measles vaccine; is that correct?

Mrs. SCHOLL. Yes. There has been so much indifference toward reactions. Doctors in the past have had a hard time acknowledging that this even happens. It is coming around now where it is becoming more accepted, and that is shown here with hearings taking place and everything that has gone on in the past year. I would say it has been better in the past 2 years, that there has been an acknowledgment that there are reactions to vaccines and not just to the illnesses themselves.

However, I would like to say that it has affected our lives. When you have a healthy, normal child, a beautiful baby, for 16 months and then she has a reaction to a shot, that I gave my daughter in good faith—and it was mandatory, anyway; I really had no choice. I was not aware of any adverse effects at the time. I, at the time, thought the vaccine program was very good, and I am not antivaccine today, either. However, there are certain fears I have.

I would like to say that these fears are not unwarranted.

First of all it appears to me that the manufactures and/or certain government agencies are intentionally withholding vital information. Not only from the public but from the medical professionals and the rest of the government in general.

I fear that one of the reasons for this withholding of information stems from the fact that these certain agencies have never, and I repeat never, conducted vaccine safety and/or efficacy studies in this country. Let me emphasize that such studies have been done in Europe for years.

If my facts are correct, I can surely understand why they would not want to publicly uncover their own incompetence and ignorance to such a major concern * * * that being every child in the United States.

It horrifies me that I have even heard remarks in reference to the cost of new vaccines and vaccine studies, which leads me to a question.

Why is it that the Government can give away billions of dollars in aid to foreign countries, and yet won't spend a dime on researching and investigating the safety of the vaccines that are injected into every child in our own country.

Anyway it was difficult to see this child when the reaction occurred. At first the doctors did not know if she was going to live. Then if she was going to live, they did not know what her mental state would be.

After the initial tragedy and illness was over, she was left paralyzed on her left side. Now I was told by a neurologist that we were a lucky victim. He had to look up 16 cases in his medical journals to find a measles reaction of this sort. He called it post-vaccinal encephalitis. He told me that out of the 16 cases since 1962 there has never been a child who turned out as good or complete as Stacy after this illness.

Needless to say, I did not feel lucky. However, I was happy my child was alive, and the prognosis was she may have a few learning disabilities; she is going to be prone to seizures; and she is paralyzed. Hopefully, she will come around and be left with a hemiparesis, which is what I call leftover paralysis, on her left side.

That was the initial tragedy. However, the nightmare was just beginning. Stacy was in the hospital for a month. Then after that I would take her to the hospital for physical therapy 5 days a week. Some of it was painful. I would have to now take her to the pediatrician, the neurologist, the orthopedist, the brace man to make a leg brace for her leg.

Giving her medication was very difficult. It was an alcohol-base phenobarbital, and it burned going down. Holding my daughter down, having her scream and cry—the mental anguish alone was enough to drive anyone crazy, let alone the financial burden that started to mount.

Now even the doctors who had made the initial diagnosis and felt strongly originally that Stacy has post-vaccinal encephalitis and they started what I call their antiacknowledgment routine. When I would bring up the illness or when any doctor would ask me what had happened, I would say, "post-vaccinal encephalitis," and they would say, "Oh, come on." I would say, "What do you mean 'Come on'?" They would say, "Well, that just doesn't happen."

As I was saying, even the doctors who had made the initial diagnosis shied away from what they had stated originally. I do have the diagnosis on a sheet of paper, so I do have it in writing. I am not crazy.

However, after that I wanted to make up stories like she was hit by a car, because nobody wanted to listen to my story. Any new doctor that we went to did not want to hear it. "Aw, come on, lady." The indifference involved in this and the intimidation I have felt by certain groups of people is what bothered me more than anything.

However, when it got to be bad, Gary and I filed a lawsuit. We figured there had been a gross injustice here on someone's part, and emotionally and financially we had been wiped out. We have been draining my in-laws and my parents ever since. I even went to Easter Seals and was turned down for free therapy there because my husbands income was over $15,000 a year. It is endless.

My daughter is now going to be 7 years old in September. We are looking forward to a heel cord surgery in October.

There are many problems when you have a paralysis with someone so young and the body is still growing, her one arm she still does not use and I doubt she ever will. It is starting to atrophy.

We have to watch out for curving-in hips. We are always on the watchout for scoliosis. I am always trying to come up with new ideas of fun things for her to do physically.

She has been exposed to adults and 80-year-old people all her life and therapy sessions. It is a little bit bizarre.

I have to say that in the county in which I live in Florida they do have a very nice program for the children now. Once they have reached school age, you no longer have to pay for private therapy. So in that respect the therapy is now coming to us free. We get bus transportation to and from the house free. I appreciate that more than anyone knows. It is a beautiful program. She gets very good therapy and is with children her own age with other problems of the same sort.

Senator HAWKINS. Who provides the transportation?

Mrs. SCHOLL. It is from High Point transportation as far as I know.

Senator HAWKINS. Pinellas County?

Mrs. SCHOLL. It is Pinellas County.

I know that we are discussing compensation here. My lawsuit, again, has been going on for so long.

Senator HAWKINS. Five years, did I understand?

Mrs. SCHOLL. Yes; 5 or 5½ years. I am a little scattered on the date.

To date, there is absolutely nothing that has come out of it. I try to keep an open mind and I try to be objective. However, it has been one circumstance of bad experiences after another.

When we talk about compensation and justice, and words such as this, I just cringe inside. I feel that if the medical community is saying that these reactions occur so infrequently, then how much of an expense could a compensation program really be? I have more questions after listening today than I have answers or statements.

I have heard things. I agree with most of the things that Jeff Schwartz said, and he stated most of what I had intended to say.

If the statistics they are looking at—in reference to HHS statement—are correct that it is only 1 in 1 million, that reactions occur then how much could that really cost in compensation versus the lawsuits and the hearings and the taxpayers' money and everything else?

I do not understand—and there has been evasive answers that I have heard all along, reading reports, documents—why there never were studies of vaccines. I just do not understand why there never had been a study before?

I am a layman. I am not a professional. I do not know, but they, the HHS are telling us that the benefits outweigh the risks. Yet, we along with them, HHS do not even know if these vaccines are that safe or what the benefits really are, what the efficacy rates are, until there is an accurate study done. Why are we giving them? This has been going on for 40 years.

They were giving some statistics that every child up to the age of 7 years old, 5 percent of them will have convulsions. How long has that study gone on since they have been giving the pertussis vaccine, is what I would like to know? Has that been going on? Is it 5 percent since the vaccine, since 1933, has been in use or was it just

recently? All children are supposed to be getting the vaccine. That could also correlate.

I do not want to sound antivaccine, but there are so many questions.

About the reporting and bookkeeping, I am from the private sector, not the public sector, so I am representing 50 percent or the other half. I feel if information were distributed through obstetricians' offices, pediatricians' offices, and let the parents have a number to call or an address to write, instead of leaving it up to the doctor—leave it up to both of them, but give the parents the option, also.

I particularly know of one case where a very dear friend of mine's daughter had a measles reaction. A seizure disorder developed 12 days after the measles shot. She reported it to her pediatrician, and her pediatrician said, "Well, I'm sorry, it didn't happen within the 7 to 10 days, so it's not from the shot." She left it at that. I said, "Are you nuts?"

This is the kind of intimidation some doctors have given to their patients or patients' parents, and some people are willing to accept that as an answer.

We have the problem of reporting. I agree that the reporting of adverse reactions has been practically nothing. I do not even know if my daughter's case went down as a reported reaction. I have no idea.

Senator HAWKINS. Does the idea of a Federal compensation system for vaccine-related injuries appeal to you?

Mrs. SCHOLL. Yes, it does. Definitely. I feel that if the Government—State, local, Federal, what have you—has committed itself to taking on the responsibility of enforcing vaccine programs prior to a child's entrance to school, then it is just logical that they must take the responsibility of coming up with a compensation program for any injured party as a result of their enforced commitment. I do not think that is wrong. I think it is just.

I have three children now. I have a baby who is due for her measles shot in 3 months. Now my first child had a bad reaction, terrible. This is the one we have been talking about. My second one, Holly, I rationalized and said, "I'm going to give it to her." It is only one in a million. The benefits outweigh the risks, the whole bit. However, I gave it to her. Five days after her shot, sure enough, fever of 104, listless. We were up with her 24 hours a day with cold packs, aspirin, Tylenol every 2 hours. I thought I was going to lose this baby. She turned out fine. That was really the extent of it. However, it is the point that Holly, my second child, never reacted like Stacy did with anything. Holly had never had a temperature over 102 in her whole life. Then with the measles she had 104. Where Stacy had reacted 104, 105 with almost anything. It was not abnormal for her.

Now the baby, Jackie, looks like Stacy, acts like Stacy, and reacts like Stacy, and I'm scared to death. I do not know what to do.

However, there is no flexibility in the law right now. Do I want to go to jail? Am I going to be criminally prosecuted for wanting to save my daughter's life by not giving her the shot, and, hence, she

is not entered into school? She will be 16 months. I think I would have a while before they would come and get me.

It is just aggravating, and I was told by my pediatrician that in 3 months is the big shot for Jackie. He really is a sympathetic man, and I really do like him. I said, "I don't think she's going to get it." He said, "Well, then she won't be allowed in school." I wanted to say, "Well, tough." I would rather have her alive.

Senator HAWKINS. Have you explored the possibility of getting a medical exemption form for that child?

Mrs. SCHOLL. I sure have. I will do everything I can because, as far as I am concerned, she will not get the shot. I just can't do it.

Senator HAWKINS. You agree with a lot of parents that have corresponded with us that there should be some emphasis on a screening process for children to see what the possibility would be if they were to get the first shot, second shot, third shot?

Mrs. SCHOLL. That is right. If there is some indication in a family, the family should be examined. There should be questions asked as far as how each child has reacted to different things. If there is some kind of incidence, there may be a different way of administering the vaccine or smaller doses, anything, just to try to help a little bit.

I know how scared I am. I have been through hell. I still feel the vaccine program is a good idea, but only if we are presenting good vaccines, good vaccine programs, and the truth about all information involved. If we cannot be honest with the parents and the public, then I think we have lost a whole lot of integrity as far as the medical profession is concerned and any other agency involved with regulating vaccines.

Senator HAWKINS. We appreciate your sharing your experience with us. It is very helpful as we devise a program of mandatory reporting, a compensation program. Your participation does lift the awareness, I believe, of parents and doctors nationwide to those isolated cases that, if indeed are so few, should not be so expensive.

Mrs. SCHOLL. That is what I am saying. If they are not so few, then obviously there is something wrong.

Senator HAWKINS. I feel keenly, as you do, about a screening test so that we do not give children the vaccine where, indeed, we know it would cause an adverse reaction.

Mrs. SCHOLL. I appreciate everything you are doing on this issue. I really do. I want you to know that. Many people do.

I also want to say that, if we all have these questions, why weren't any of these things thought of originally? Why wasn't there a screening program? Why isn't there one now? Why isn't there some kind of test? Why?

All we hear is evasive answers or "It's being studied." It is always being studied. We never get any conclusive information.

[The prepared statement of Mrs. Scholl follows:]

PREPARED STATEMENT OF WENDY SCHOLL

My daughter Stacy, born September 12, 1976 was a beautiful healthy baby until eight days after her measle shot when I noticed she had a temperture of 102 degrees. I did'nt think too much of it yet I called the pediatrician anyway; he said "not to worry it's her reaction to the measle shot and she will probably get a little rash, but in a day or so it will disappear." I was not terribly concerned at this point. Yet she had a fever through the night and the next day January 25, 1978, she had a rash. That night Stacy was very fussy and awake till two in the morning. We gave her some asprins and put her to bed. January 26, she was sleeping late and I did not think much of it - finally I went into her room to find her panting, eyes affixed and a pool of blood on the sheet where her mouth was.

I called an ambulance - due to a tremendous snow the night before we were unable to go to the hospital where our doctors were on staff. When we arrived at Holy Family Hospital, Stacy was convulsing with a temperature of 107 degrees. The emergency doctor wanted to know what was wrong with her. I replied "as far as I know it was a reaction to her measle shot. His first reply was, "That just does not happen from a shot." Then I asked if she was going to live, his reply was not comforting, "She is a very sick little girl, I do not know." Next they called in a pediatrician. The pediatrician wanted a spinal tap to check for menigitis. Nexy they called in a neurologist. I told him my story of the shot, and his reply was "I do not think this could be from the shot, it is so rare."

However, my daughter by this time was given a dose of valium, and hooked up to a breathing respirator, heart monitor, cathatorized and put into intensive care. The neurologist wanted to take an EEG. The results were severely abnormal on the right side of the brain.

I had asked what this meant, hoping all along that this was just a severe fabricle convulsion, but I was told that if it were the EEG would have shown a general abnormality not focal. Next, the neurologist wanted to check for signs of a tumor with a CAT scan. The results were negative. During this time the doctors came to me and stated, "Mrs. Scholl, we do not want to give you false hope. We now think it is a viral infection of the brain - encephalitis." At this point Stacy's kidneys started to fail, her lungs filled up, she was having siezures and a temperature of 104 degrees. By this time the doctors had told us that Stacy is paralyized on her left side and this was minor compared to what they were really worried about.

January 27, Stacy was still unconscious and the doctors kept telling us not to have false hope, that this is not a good situation. The nurses could go in her room to pinch her just to get her to cry. Sunday is blurred, however, I was told they were going to take another EEG tomorrow. I wanted to know why and they told me that they wanted to see if there was any change in it - either worse or stable. I wanted to know if it would show improvement and they said no just stable, because clinically the brain would not show improvement for weeks even if there was some. The results were optimistic. They could not figure it out - "there was improvement on the EEG".

By this time Stacy's vitals had improved and she was pulled off the machinery. However, the doctor said, "now when she comes to we just hope she recognizes you." What a terrifying thought that she would not. That night Gary ahd I stood over her crib. Stacy opened her eyes consciously for the first time since this nightmare

began. She reached up with her one arm and squealed mommy. I wisked her out of the crib, Gary and I embraced her and we cried.

Stacy's face drooped so bad on her left side - she could not get her head straight, it as twisted to one side. She could not roll over or sit alone, let alone walk.

I remember asking for a physical therapist and hounding her if Stacy would walk again. She replied, "She has to learm to crawl first." Reality was beginning to sink in. The life and death tragedy was over, but the nightmare was just beginning.

Stacy's neurologist came in and said to me, "I want you to know how lucky you are. I had to consult my medical journals to find similar cases and there have only been sixteen since 1962 and none of them has turned out as well has Stacy, post vaccinal encephalitis is so rare."

Emotionally we were all wrecks. Stacy was so frustrated, she would look at her arm and cry. She started biting. Stacy spent a month in the hospital recieving therapy. She had a brace put on her foot and recieved 60 mlg of Phenobarb a day to prevent seisures. By the time she left we had been befriended by everyone in the hospital. Stacy was sitting and could pull herself to a standing position.

We returned daily for therapy. She recieved electric stimulation which made her cry. I felt my heart was being ripped apart piece by piece. Now monthly visits to the pediatrician, the neurologist, the brace man and daily therapy. When I would mention to any doctor that I would come into contact with what happened to Stacy, they would look at me as if I were nuts. Even the doctors that made the diagnosis would shy away from saying "post-vaccinal encephalitis." Only my relatives who are doctors and personal friends of ours that were doctors would admit this happens. It got

to the point I wanted to say she was in a car accident, that way we would be recieved better. As the months went on, I was taking Stacy to therapy daily and the bills were mounting. We were afraid to leave Stacy with a sitter for fear she would have a seisure And getting her medication down her was a real trick since it was an elixor it burned going down. I would have to hold her down and fight just to get it down and she would scream and cry every time. I could not take the pressure. I lost 15 pounds, I was spotting, and I was going numb on one side of my body. After seeing a doctor he told me "You won't let yourself have a mental breakdown so you are having a physical breakdown. I realized that I had to lighten up. Tension between Gary and I had mounted due to the fact that I felt I was carrying the entire load of dealing with the doctors, the therapists, and the bill collectors.

We decided to contact an attorney to start litigation. An attorney thought it was going to be difficult, but he felt and we felt that we had been wronged.

Stacy started walking and life started looking up. I was now pregnant. I had enrolled Stacy in a 0-3 program gearred for children whom had a trauma, injury or birth defect, that would result in slow development. Stacy and I would drive 15 miles two days a week for that and three days a week I would take her for therapy.

Everything was going somewhat smoothly when winter came again. The snow was herrendous and sub zero temperatures. I would have to carry Stacy, I was pregnant, I would slip once in awhile, but it got down right trechorious when I would have to carry her 300 yards in sub zero to therapy while I was now seven months pregnant.

Then my husband lost his job, practically the worst thing to happen because we lost our insurance. Then I delivered Holly one month early. We decided to move to Florida, at least we would not have to put up with the cold.

Since Stacy has a pre-existing cause, she is un-insurable for at least one year.

One of the first things I did was go to Easter Seals. We were turned down for aid becuase Gary made over $15,000. So, I tried Morton Plant Hospital two days a week. Now it was harder with a baby and a two and a half year old who needed to be carried alot. Then we tried private therapy. I have had Stacy evaluated every year since she has been two. She always turned out with average intelligence but needing normal socialization with other children, something she had never. So, I enrolled her in nursery school. Here she had a lot of emotional problems. She had always been the center of attention in a totally adult world. I found doctors that I loved and we began feeling comfortable in Florida. At least I found people in Florida more understanding and compassionate.

Holly had her first DPT and did not even run a temperature. I was thrilled, so by the time she as due for her measle shot I had rationalized that the only time Holly had a fever was when she was six months old with an ear infection and it was 102 degrees. Whereas Stacy ran 104-105 with almost everything from a cold to Rose~~ita~~ola. I also felt that this reaction happens only one in a million. Well, ~~six~~ 5 days after her shot she ran a temperature of 104 degrees for four days and was listless. I ran like a lunatic screaming and crying, "I am killing my baby, why did I give her that shot." Anyway, ironies of ironies on the tenth day of Holly's shot, was the day we were giving our depositions to the pharmacutical companys attorneys

for Stacy's law suit. I did not want to leave Holly with a sitter but this was something I could not back out of. Needless to say I was a bit testy all day. We brought Stacy with us. During my two and a half hour interrogation, the attorneys wanted to know my family history, if there was any epilepsy, etc. However, his intimidating style of questioning did not bother me until he started asking me, "Who told you you had to get your daughter this shot?, Did you call up the pediatrician's office and ask specifically for the measle shot?" I said no, it happens to be only one shot in the required series of vaccines given. He then replied, "Who told you they were required", "Where did you get that idea", and "Required for what?" I think I almost lost my cool. I stated, "on T.V. they have commercials." Then I stated that in order to get into school you must produce a vaccine record. I told him that I took it as common knowledge and as a concerned parent I felt I was doing the right thing.

All I kept thinking about was Holly. So after this we rushed home and when I picked up Holly, she was covered in a lovely rosy red rash. I got on the phone to my pediatrician and gave a few . . . his comment was something like your kids react strange to this shot, but try not to worry because her fever has broken. Well, Holly did make it OK, but Gary and I have a few more gray hairs. After a few years of nursery school Stacy was ready for kindergarten. So, I took her to the school eight months before school started to see if they would have any problems accepting her. They said no problem but why not go ahead with a complete evaluation, so we did, along with recommendation from pediatricians and neurologists. It came out the same, "normal school setting, but she needs therapy."

So we had her put in private therapy after school. The poor kid was pooped. However, for the first time we ran into a new problem - her teacher Mrs. G. was a woman who had been teaching for forty years and never had a handicapped child. This woman was not well liked by anyone yet she really had it out for us. She had sent the Public Health nurse out to our house one day because Mrs. G. could not believe that we had ever given Stacy therapy, because if we had why could'nt she use her arm... I asked the nurse if she had gone to Stacy's two inch file located in the principal's office. Her reply was as I expected, "no". She left feeling extremely embarrassed. I then called the principal and wanted Stacy moved into the other kindergarten and her reply was "no." Then I had a conference with Mrs. G,, She was a little more willing to try. For instance, she would tape Stacy's paper down to the desk so she could write. She was starting to come around. But she kept saying to me, "you should really send Stacy to Eisenhower Elementary where they have a wing for the physically impaired." I did not want that because Stacy was recieving therapy privately and she was going to have to grow up in the real world. And we were constantly striving for normality.

I thought everything was going well until January or February 1982, when I got a letter home that Stacy might be retained in kindergarten next year. So here's my next conference. Mrs. G. said to me, "Stacy's Santa Clara test scores have not gone up much since the beginning of the year." Then she said that "you and your husband should go for counseling." I said why and she said, "well because Stacy is so frustrated." I said, "Can't you see why she's frustrated?" Then I changed the subject back to scores and I said, "Well, what has'nt Stacy improved in?" Out of approximately 28 things she had improved in all but two. Now I started getting

angry. Especially when it was hearing and visual memory. Then Mrs. G. said, "I think Stacy is emotionally handicapped." I asked her to explain to me what that meant and she said she could'nt. Then I said, did you ever consider Stacy might have a hearing or seeing problem or that maybe this could be a learning disability and how dare you label my daughter something when you can not even tell me what it means. I ended up by saying, "Look, if Stacy has to be held back next year, so be it, but I am not going to let you be the only judge in this decision." I went home and phoned the principal and demanded a staffing of the social worker, guidance counselor, psycologist and the speech teacher, plus three professional evaluators from ADAPT, Childfind, Fiddles. After a two week complete evaluation observing Stacy in the class room, the recommendations were that Mrs. G. owed me an apology. Stacy was definitely first grade material and they could not detect a learning disability. However one of the evaluaters told me on the side, "that we should look into Eisenhower, it has great teachers who would be very understanding plus we would not have to pay for therapy."

Needless to say I never recieved an apology and Gary and I decided to look into Eisenhower. It looked beautiful. They had a very mild handicap class where Stacy would be and she would be main streamed. She would recieve PT and OT every day. The only downfall was the 40 minute bus ride. Anyway, we tried it out for summer school and it proved beneficial. When fall rolled around Gary and I were amazed, she was reading and writing and doing math. Stacy's report card at the end of the year was so impressive I wanted to publish it in every major newspaper. Today I thank Mrs. G. for the misery she put us through, because Stacy is proud of herself, as we are of her.

Now, we are facing a heal cord surgery that means a cast for six ~~months~~ weeks and then a brace. She will be covered partially by insurance in October, so we are waiting for then. We have to keep an eye on her posture, the way her feet are positioned. There is always the concern about scoliosis.

I have heard both sides to this issue. I feel I have tried my best to be objective. After this happened to Stacy I rationalized that it was one in a million, then I gave it to Holly and she reacted severely (104 degrees, listless four days, cool packs, aspirin, and tylenol). Now I have a third daughter, Jaclyn and with all my heart and all my soul, if I allow her to have this shot, it would be as if I wrote out her death ~~waiver~~ warrant.

I feel that if you have such a good argument than why, why, has there never been a safety study done on these vaccines. What does this tell me about our government standards and the medical profession? It is not a pretty picture. Please correct me if I am wrong, but I was under the impression that the laws of the U.S.A. were set up to protect the innocent and the helpless, and who could fit that description more than babies and infants?

There must be a way that parents can report a suspected reaction because I do not feel confident that doctors will really acknowledge this fact.

Senator HAWKINS. Hopefully, we will.

Thank you so much for helping us.

We have Mr. Robert Kaufman sitting beside you, who is a specialist, a trial attorney, in this particular field of practice.

Do you have a statement, Mr. Kaufman?

STATEMENT OF ROBERT KAUFMAN, TRIAL ATTORNEY, GAYLORD, MICH.

Mr. KAUFMAN. Yes, I do. Thank you, Madam Chairman.

My name is Robert Kaufman, and I am a lawyer practicing in Gaylord, Mich. I am representing a number of children who, we are going to be proving, are victims of central nervous system complications of vaccination. Some of those children developed brain damage secondary to the pertussis component of DPT vaccine.

What I want to tell this committee about right now is the experience of one of my clients who did not receive a vaccine. Nevertheless, I think my point will be pretty clear.

I am representing a young man who was a combat soldier, a veteran of the Vietnam conflict. He was involved in a five-man search-and-destroy mission near the demilitarized zone. He came into repeated contact with a product of the Dow Chemical Corp. known as agent orange. Ten years after he returned from the battlefield he developed a highly debilitating agent orange syndrome. The man is physically disabled. His doctors do not believe that he will ever be able to work again.

My client and I applied to the Veterans' Administration for service-connected disability benefits. Over the ensuing 2 years we exchanged a large volume of paper with the Veterans' Administration, which finally precipitated their convening of a hearing in Detroit.

At the beginning of this hearing one of the members of this three-man tribunal saw fit to call to my attention a fact of which I was already well aware, that there was a $10 limitation on attorney fees for representing my client. He asked me whether, in view of this fact, I wanted to withdraw. There we had an employee of the Veterans' Administration attempting to cajole me into abandoning my client.

During the course of this hearing I repeatedly referred to the three judges as "Your Honor," and they told me that that was an unnecessary formality. They told me, "Mr. Kaufman, this is not an adversary proceeding. This is a helpfulness proceeding." I will tell you how helpful it was.

Three weeks after this hearing we got a decision in the mail advising us that agent orange was strictly a weedkiller; that it was not connected in any way with any form of human morbidity; and that, consequently, my client was getting nothing.

In the course of this hearing we presented all of my client's medical records. His doctors were unanimous that this man is disabled. Only one of these physicians expressly addressed himself to the issue of whether dioxin poisoning caused my client's injuries, and he answered that question, "Yes, it did." That meant that we had an uncontradicted administrative record of service-connected disability.

The Veterans' Administration, nevertheless, told us to take a hike. They could do that with complete impunity because they know that their findings of fact are not subject to judicial review, no matter how unwarranted by the evidence, no matter how patently illogical, no matter how utterly preposterous. That is what they did to us.

Now I am representing about a dozen children who have gotten different kinds of central nervous system damage from vaccines. It is on their behalf that I am here to ask this committee today, please, don't put infant victims of vaccine complications in the same kind of a mess.

All these features, statutory limitation on attorney fees to $10, the nonadversary character of the proceeding, the abrogation of technical rules of evidence, the elimination of judicial review of administrative fact finding, were all sold to the Congress of the United States on the theory that they somehow help the veteran. I am here to tell you they don't.

If a similar mechanism is created for the ostensible purpose of helping vaccine victims, the same thing is going to happen again to them. I know what I am talking about because I have seen it myself.

Senator HAWKINS. Under the present system, is there any practical way for a vaccine manufacturer to avoid civil liability for breach of the common law duty to warn the end-user or the vaccine recipient?

Mr. KAUFMAN. Yes, there is, Madam Chairman. In fact, they already do.

When a manufacturer of vaccines sells in bulk to the U.S. Government, the manufacturer requires as a condition of sale a contractual undertaking by the United States to provide the so-called important information sheet, the written warning, to the parent or guardian of each vaccinee. The United States, through the Center for Disease Control services, distributes pediatric vaccines, particularly measles, mumps, and rubella vaccines, to State and local health departments all over the United States under grant programs or under cash purchase assistance programs.

The Federal Government, the Center for Disease Control, imposes a similar stipulation in its dealings with State and local health departments. They, the immediate proprietors of the mass vaccination clinics, are contractually obligated to make good on that promise that the parent will get the important information sheet.

Under a precedent created in the case of *Reyes* v. *Wyeth Laboratories*, the vaccine manufacturer is legally responsible for seeing to it that the parent gets an adequate warning when the vaccine is distributed in a mass vaccination context, without an individualized expert determination by the physician of relative benefits and risks.

If, to take a hypothetical example, Merck, Sharp & Dohme is sued because some local health department in Iowa didn't bother passing out the important information sheet, Merck's remedy is very clear. Their remedy is against the United States because the United States promised to make sure that that warning would be given.

The United States has recourse as well because the State or local health agency made a similar promise.

There is a way that manufacturers can and do protect themselves against common law liability for breach of the duty to warn. This is not something that couldn't be done. It is something that is already being done.

I might add, however, that it has not ended the debate as to the adequacy of the warning that is now being given on that particular product.

Senator HAWKINS. What would be the likely consequence of abrogating vaccine manufacturers' liability for a breach of the duty to warn of adverse reactions?

Mr. KAUFMAN. I am glad that you asked me that question, Madam Chairman, because the funding mechanism that has been proposed this morning is, in effect, to declare that the entire pharmaceutical industry has to pick up the bill. The proposal has been made that these damages shall be paid for through a surcharge on the sale of all vaccines by all U.S. manufacturers. Madam Chairman, we regard that as extremely dangerous.

It is only one of the purposes of the tort system to protect people who have already suffered physical injuries. It is a very important purpose, but it is only one of them.

Another one of the purposes is to supplement our criminal statutes by encouraging people to behave in a way that does not threaten the lives and health of others. It has to be that way because civilization, as we know, would crumble if there were not individual responsibility on the part of every act or for the natural or probable results of his actions.

Now if you eliminate individual manufacturer financial responsibility for adverse reactions, I can envision several consequences.

The manufacturer who has a multiproduct line—some of the vaccines are very safe and some of them are highly dangerous—from that manufacturer's point of view, the sale of one is just as desirable as the sale of another.

The manufacturer who has an excellent safety record will be liable dollar for dollar on his gross revenues to the same extent as an irresponsible purveyor of dangerous goods.

The effect of the proposal that we have heard this morning is to attenuate the incentives for responsible behavior.

Senator HAWKINS. Since you represent children and parents who have claims against vaccine manufacturers, do you have any average length of time it takes to settle this question in court?

Mr. KAUFMAN. It is about 3 to 5 years. That is a pretty good ball park figure. We are talking an enterprise that requires the investment of thousands and thousands of hours of attorney time. For instance, the taking of depositions of responsible employees of the manufacturer's vaccine laboratory, that may take me to Philadelphia or upstate New York or Swiftwater, Pa. You have to take depositions of the people who the defendant is going to summon at the time of trial, who will testify that your child is really not a victim of an adverse reaction to a vaccine at all. You have to find out the factual basis for his opinion.

Senator HAWKINS. What about Mrs. Scholl's case where she immediately was given the assurance by the physician that the child was——

Mrs. SCHOLL. That doesn't make one bit of difference what is on those.

Senator HAWKINS. I heard you say you had to explore——

Mr. KAUFMAN. From a legal standpoint, an ex parte interview between the physician and the patient does not count for a whole lot. Mrs. Scholl, in her lawsuit, could not prove that her child is a victim of vaccine-induced injury by getting on the witness stand and saying that her doctor told her that. The reason, of course, is that that is hearsay. The defense could not cross examine to determine the factual basis for that opinion simply by questioning Mrs. Scholl because she is not the one who said that. What would count is what her physician says.

As Mrs. Scholl told you, what the physician says at the initial interview and what he is willing to say on the witness stand can turn out to be two very different things. That is only one of the considerations that makes vaccine product liability litigation an extremely complex, extremely demanding, and very expensive enterprise for the attorney and the client as well.

Senator HAWKINS. In your opinion, who should bear the financial burden of vaccine-induced injuries?

Mr. KAUFMAN. In cases in which the injury results from culpable misconduct on the part of the manufacturer, the manufacturer should bear that burden. I think it is unconscionable to shift that burden to some other manufacturer who did not make the shot, and even more irresponsible to declare that the taxpayers should have to pay for that.

Now it has been suggested that a no-fault system would be desirable to spare the parents the burden of proving fault. My own impression is that hasn't been a problem for us yet. Whatever other problems we face in our cases, I do not expect to have any difficulty showing culpable misconduct.

One of the purposes of this hearing was to consider DPT vaccine in particular. I would like to go on record as saying that in all of these cases, in any DPT vaccine case, I think the lawyer who uses his head will discover that he will have no problem proving fault. Let me tell you why.

The precursor of modern DPT vaccine has been around since the beginning of this century. The organism Bordetella pertussis was isolated and characterized by two French scientists by the name Bordette and Gengou. They established the laboratory conditions under which this organism could be grown in the laboratory outside of the human body on a blood agar substance known as Bordette-Gengou medium. It was they who developed the first primitive pertussis vaccine consisting of washed, killed cells that had been grown on this medium.

With minor modifications, the vaccine was introduced to the United States by the Michigan Department of Public Health in the early 1930's. I suggest to you, Madam Chairman, on the basis of my own investigation, that since those days no significant changes have been made in the vaccine used in this country.

Until about a year ago, when NBC News did a story on it, manufacturers were doing essentially nothing in the way of improving this extremely primitive vaccine.

You have heard witnesses from the U.S. Public Health Service assure this committee that manufacturers are working responsibly to try to improve DPT vaccine. I suggest to you that should be taken with a grain of salt. Those witnesses were unable to supply you, Madam Chairman, with any kind of particulars or concretes to justify that statement at all.

I think this committee should be aware of the difficulty, the extreme resistance that I have been getting in our litigation from manufacturers to show me what they have been doing for the past 30 or 40 years in the way of research and development to try to improve this vaccine. So far, I have not been able to get anything from any of the manufacturers except stall tactics, and I will take an educated guess why. Because they have been doing nothing until very, very recently to make this vaccine better.

That is why I say that proving negligence is no serious problem. In any case where it is proved, it is the manufacturer, and not the taxpaying public, that should pay.

Senator HAWKINS. Would you be opposed to an elective, optional compensation program?

Mr. KAUFMAN. Provided that it were truly elective, no. I consider the right to trial by jury to be an extremely important right. It is the product of centuries of legal evolution. I do not think that it should be lightly discarded. I do not think that parents should be deprived of their freedom of choice.

However, if you are going to widen the range of alternatives available to parents, from their perspective I would say that that is just fine, as long as it really is truly elective.

If this hearing is going to result in a bill, I think that special pains should be taken within the bill itself to make sure that it really is elective. This is something that is simply too important to be left to administrative rulemaking, especially if the Department of Health and Human Services is going to get a grant of rulemaking authority under such a bill.

Senator HAWKINS. That was one of my questions. Should the Secretary of HHS be disqualified from involvement in compensation of vaccine injury victims?

Mr. KAUFMAN. Positively. Might I cite two illustrations that I think will lead this committee to the conclusion that for the Secretary of Health and Human Services to direct such a program would entangle it in an extremely serious conflict of interest?

Mrs. Scholl has told you about her unfortunate experience with the live, attenuated measles vaccine. That product was introduced in 1963. This vaccine contains live measles viruses. They are industrially modified by a process known as attenuation. Very simply stated, the vaccine virus is adapted so that it will grow in chick embryo tissue culture, which the wild virus, which is responsible for measles contagions will not.

One of the concerns of the medical community is that, because it contained a live virus, this vaccine might be objectionable and dangerous for the same reason that measles itself is a dangerous disease. The rationale for measles vaccination does not consist princi-

pally in the fact that it makes the child sick for 2 weeks or it gives them a red rash. The rationale for prophylactic vaccination is the neurologic complications.

The question arose, if the epidemic measles virus can cause neurologic injury, is it not reasonable to suppose that a live measles virus vaccine could do the same thing? The Nation's epidemiologic authority is the Center for Disease Control. It was to them that the medical community and other concerned citizens should properly be able to look for answers.

The Center for Disease Control has undertaken to provide an answer. I will tell you that it is grossly unsatisfactory.

The Center for Disease Control issued a series of publications called, The Measles Surveillance Reports. In these reports they undertook to describe what they claimed was all known cases of neurologic injuries secondary to measles vaccination. They used definite criteria to decide what were such cases. The case had to be between 5 days and 30 days after injection. It had to be clearly neurologic in nature, and there had to be no plausible alternative explanation for the recipient's illness. In other words, if there was a suggestion that something else was involved, they gave the benefit of the doubt to the shot. So be it.

Based on what they said were all the known reports meeting this criteria, in the measles surveillance reports the Center for Disease Control announced the conclusion that the rate of neurologic complications of measles vaccination was in the range of one per million.

I represented a plaintiff in a measles vaccine case in Crawford County Circuit Court in Michigan which was settled 2 weeks before trial. We subpenaed all of the records in adverse reactions of one manufacturer, Merck, Sharp, and Dohme. To those records, we applied CDC's same criteria: onset between 5 and 30 days, a clearly neurologic character of the reaction, no obvious alternative explanation.

For every such reaction which CDC claimed was all of the known reactions, we found in the files of this one manufacturer over two reactions, 2 to 1, that CDC never reported. I leave it to this committee in its wisdom to decide whether that represents honest epidemiologic incompetence or whether, as I suggest, the Center for Disease Control was taking sides by deliberately underrepresenting the incidence of measles vaccine morbidity. That is one example. Here is another.

I am talking about the rubella vaccine. A synonym for rubella is German measles. The first rubella vaccine was marketed by Merck, Sharp, and Dohme with a seed strain virus that was developed by what is now known as the National Center for Drugs and Biologicals, but what was then known as the Bureau of Biologics. That was Meyer and Parkman's HPV 77 rubella virus. It was developed by Government scientists with Government funds and used by Merck, Sharp, and Dohme in the first rubella vaccine.

I believe it was in 1979 that this particular virus was discarded because of the apparently transitory character of the immunity which it confers. A little girl who receives the shot is likely not to immune to rubella by the time she receives adulthood.

Merck, Sharp, and Dohme announced, when the widespread use of this new rubella vaccine began, that in collaboration with the Bureau of Biologics it had collected a card file of 2,000 recipients of the vaccine for long-term longitudinal studies; that years in the future they were going to, at various intervals, look up these young recipients of the vaccine and see whether they were getting a disproportionate incidence of any kind of morbidity that might suggest a relationship to the shot.

Some acquaintances of mine attempted to determine the status of this long-term, follow-up study. Our inquiries to Merck, Sharp, and Dohme were parried with the suggestion that we ask the Bureau of Biologics because they were the sole custodians of these file cards.

Our attempts to get this information from the Bureau of Biologics were more or less fruitless. When the last letter was written, what it came down to was this: They have the file cards. They have done nothing with these file cards. They do not know whether they intend to do anything with the file cards in the foreseeable future, and that they cannot promise that they ever will.

My first example pertained to the Bureau of Biologics, which is responsible for epidemiology. My second example pertains to the Bureau of Biologics, which is responsible for vaccine safety. Both of these are member agencies of the Department of Health and Human Services.

Aside from its epidemiologic responsibilities, the Center for Disease Control is also in the vaccine-promoting business. If you have ever seen those Star Wars posters in your doctor's office that say, "Mothers of Earth, get your children vaccinated," you will know what I am talking about. Those are a product of the Bureau of State Services of the Center for Disease Control. That is just one of many things they do to push, to promote vaccine, to achieve the widest possible use of the product in this country.

The Bureau of Biologics has other responsibilities besides vaccine safety. They are also in the research and development business, researching and developing new vaccine viruses.

I do not think that it would be a safe state of affairs to make this Agency, the Department of Health and Human Services, the Agency that will declare on behalf of the whole U.S. Government just how often serious adverse reactions to vaccine occur. I would suggest to you, based on these two examples, that that would be somewhat analogous to putting Al Capone in charge of alcohol tax enforcement. Every time they acknowledge that such a case occurs, they cast doubt on the wisdom of their own regulatory activities.

Senator HAWKINS. Thank you, Mr. Kaufman and Mrs. Scholl. You have contributed much to this hearing. We look forward to working with you.

We will excuse you at this time.

I want to thank everyone who helped us today.

Mr. KAUFMAN. Before I go, Senator, with respect to the anecdote about the Bureau of Biologics, this committee does have subpena powers. If the committee is considering exercising them, it might profitably summon for questioning a Dr. Paul Parkmann, P-A-R-K-M-A-N-N, and Mrs. Hope Hopps, H-O-P-P-S. They, we believe,

would be the two employees most knowledgeable about that episode.

Senator HAWKINS. Thank you very much for your help.

Mr. KAUFMAN. Thank you.

Senator HAWKINS. We appreciate that.

From that and previous hearings, I think we have learned that, because our own adverse reaction reporting system is voluntary and very passive, the number of cases reported really does represent a very small fraction of the total number of reactions, and that no firm conclusions can be reached about any adverse reaction incident rate.

I have also learned that another major limitation of our surveillance system is that it does not record information on the manufacturer of the vaccine used, as we have discussed today. I must say that, given the level of sophistication of our society, I find this startling and disturbing. It is a scenario that cries out for improvement.

I think we need to seriously consider mandatory reporting systems as the only possible solution.

I am most appreciative of the comments of all of the witnesses on the desirability and feasibility of a system to compensate victims of vaccine-related injuries. I would like to work with all of you on a fair and just system.

The unfortunate victim of vaccine injury should not be expected to pay the full penalty price of a benefit that is shared by others.

Thank you very much.

At this point I order printed all statements of those who could not attend and other pertinent material submitted for the record.

[The material referred to follows:]

STATEMENT

BY

CONGRESSMAN DANIEL A. MICA

BEFORE THE

COMMITTEE ON LABOR AND HUMAN RESOURCES

UNITED STATES SENATE

WASHINGTON, D.C.

JULY 22, 1983

I am pleased to have the opportunity to address the Senate Labor and Human Resource Committee, as I did last May. I am also pleased that this committee will be examining the recently released interagency study into the development, production and usage of the pertussis vaccine.

As many of you may know, my involvement in the pertussis controversy is very personal in nature. Two of my cousins have been left mentally retarded as a result of adverse reactions to the pertussis portion of the DPT vaccine. Since coming to office in 1979 I, too, have actively sought congressional and administrative action to address potential problems with this vaccine. Last April, I had the opportunity to introduce H. Con. Res. 313 which requested appppropriate House committees to begin oversight hearings and for appropriate government agencies to initiate a study to identify hazzards involved with the production and use of this vaccine. This bill was eventually included as an amendment to the 1982 Health Research Extension Act and passed the House; but for various reasons, died in the Senate. However, I am pleased that the study at issue today has come to fruition. This amendment has also been added to the 1983 version of this bill along with a provision calling for additional study if the criteria outlined are not properly addressed.

I was extremely touched by a special which aired during April of 1982 on WRC-TV in Washington called "DPT: Vaccine Roulette". The DPT problem had been brought to the attention of Lea Thompson

and News Center 4 by my uncle, Dan Rescinitti, whose sons were victims of side-effects from this vaccine. I was pleased with this report and I commend the News Center 4 staff for the fine work they did in bringing this matter to the public's attention. Segments of this show were aired nationally on the "Today" show. Following this show, my office received hundreds of calls from individuals who were concerned about this matter. I also had the opportunity to address the House and remind members of their responsibility to determine whether or not the purtussis element is safe, and if not, take appropriate steps to make it safe.

It is vitally important that our government take measures to help inform the public and medical community of potential dangers associated with the pertussis section of the DPT vaccine. Doctors should be aware of the warning signals of adverse reactions and familiar with the warnings printed on vaccine labels. Parents also should be made aware of what symptoms to watch for relating

to possible problems. Most importantly, I feel doctors and parents should communicate openly about the potential and actual reactions to this vaccine. Additionally, I would urge the committee to effectivley address the issue of compensation for victims and families of those victims left disabled because of this vaccine.

I would like, at this time, to commend the Senate Labor and Human Resources Committee for holding these hearings which will further examine the findings of the interagency group's study. Let me say that it is my major concern to see that the youth of our nation are ensured of the safest pertussis vaccine possible in order to avoid further needless tragedy.

I respectfully charge you to thoroughly examine all issues surrounding this matter and as experts give their testimony and answer questions, I would expect that the requirements outlined for this study be properly satisfied and addressed. In the event that the criteria is not met, I would vigorously support implementation of another study.

Thank you again for giving me the opportunity to address this issue which is so important to our nation's families and the welfare of our children.

S T A T E M E N T

by

Mrs. Marge Grant

Mother of Scott Grant, a DPT Vaccine Victim

and

Chairman, Research Committee Of Citizens For Free Choice

In Immunizations, State Of Wisconsin

to

Chairman, Senator Paula Hawkins

COMMITTEE ON LABOR AND HUMAN RESOURCES

UNITED STATES SENATE

WASHINGTON, D.C.

July 22, 1983

I appreciate the opportunity to present for this hearing record views and recommendations that my husband Jim and I believe are essential and must be addressed and implemented immediately if indeed this country's children are to be "truly protected" --- not only from childhood illnesses and disease --- but even more so --- from the powers that be.

Please allow me to first give a brief account of just a few of our personal vaccine encounters which will enable better understanding of why politics and science cannot be combined --- and why we've made the recommendations that follow.

You will recall I testified at your May 7, 1982 hearing about our devastating vaccine experience and it is of course because of this personal tragedy that I have become so deeply involved in study and research of the many entangled inequities in this crucial issue that literally affects every child in this country. While you may find these comments somewhat unusual and of stronger language than others at this hearing, please keep in mind they are based on the firsthand knowledge and perception we've gained from the past 22 mighty tough years of actual experience of coping with, and caring for in our own home, our totally dependent son Scott, who in 1961 suffered severe irreversible brain damage from the DPT vaccine called QUADRIGEN. This grossly defective vaccine was manufactured by Parke Davis and Co., in Detroit Michigan. And while Parke Davis must certainly be faulted for negligently marketing this highly toxic vaccine, the fact cannot be ignored that our governmental vaccine regulatory agents, who are tax paid employees and have the specific responsibility to society to insure that only "safe and effective" vaccines are allowed on the market, saw fit, to irresponsibly release this poisonous vaccine onto the commercial market, knowing full well it would seriously injure countless innocent children.

At a minimum, it was the government's duty to force a "recall" of QUADRIGEN, but instead, the grim facts were silenced.

We shiver with agony to think this slipshod operation of 24 years ago continues yet today, and wonder how many more precious children will be allowed to be maimed and killed before teeth are put into the law to make the unconscionable vaccine officials accountable for their past --- present --- and future actions.

Back in 1961, the vaccines' use and the benefit/risk ratio was propagandized as it is today, and for the first seven years after Scott's injury we believed that ever so rarely, like once in a million, or less, a person would be allergic to certain vaccines and would suffer adversely. We thought Scott was that one in a million. Until our extensive travel to obtain the best treatment possible to rehabilitate his once whole and healthy body, put us in touch with many other parents whose children also had suffered brain damage from the DPT shots. We then began comparing notes and spent much time in the medical libraries every chance we got. It was with the added knowledge (and documentation) from the medical literature of the MANY INJURIES that were indeed occurring from these crude vaccines, that we proceeded in an attempt to gain redress through the courts. And it wasn't until we were preparing for Scott's actual trial in 1975 that we were introduced to the ultimate, in corruption. Again, by none other than "our government vaccine officials" when, for reasons known only to them, they chose to cover-up for Parke Davis --- instead of helping Scott. I refer here of course to when Scott's attorneys were informed shortly before trial by Mr. Ray Crossley, the Freedom Of Information officer, that the government's testing records of Parke Davis' QUADRIGEN protocols, toxicity tests and adverse reaction reports, had suddenly <u>VANISHED</u> and would <u>NOT</u> be produced, as had been earlier promised.

At this point in time the Bureau of Biologics was under the direction of Dr. Harry Meyer who just a few months later was also one of the leading architects of the deceptive swine flu program, during which time the only scientific voice "against" the use of the swine flu vaccine, was that of Dr. J. Anthony Morris, an eminent virologist who you will recall was fired for telling the truth! Small wonder then, that Dr. Brandt and his interagency officials did not want Dr. Morris in attendance at the meetings early this year where the study you ordered on the pertussis vaccine issues were discussed. I vividly recall during the tremendous sales-pitch of the swine flu hoax, it was also Dr. Meyer who received the first dose of swine flu vaccine given by Secretary Cooper (with great publicity). Later it was discovered, that Dr. Meyer had received a shot of the "wrong strain" produced by none other than our good friends, "Parke Davis." On the other hand, for all we know, "that shot" may well have been nothing more than perfectly sterile water.

I've made mention of the above true episodes because they alone more than substantiate the fact that "politics and true science" --- simply do NOT mix!

Never did we dream when Lea Thompson's office contacted us for the story about Scott's injury and our DPT vaccine research information, that it would result in the hour documentary, "DPT: VACCINE ROULETTE" --- a most appropriate title! The showing of that film, plus our appearing on other national television shows, have put us in touch with an incredible number of families with children hurt by DPT shots. The popular television host, Phil Donahue, invited our participation on his show last December, and as a result of my request on that show alone, hundreds of letters were written.

Because of the faith those parents had in me, in them sharing their personal stories --- I shall most respectfully protect their confidentiality. But I can tell you most assuredly that the Grant family of Beaver Dam Wisconsin does not intend to leave this information go to waste or somehow have it misconstrued.

As for the Academy of Pediatrics' Compensation Proposal Scheme: It's a disgrace and an insult to the children of America. Any compensation plan whereby the liability is not placed on the pharmaceutical company, the top governmental vaccine officials, personally, or the physician who administers the vaccine, will do more harm than good. The real fact of the matter is, it will "justify" maiming and killing. And quite frankly I can't think of any better way to encourage the, "powers that be" the continued excuse to use unsafe and ineffective vaccines.

R E C O M M E N D A T I O N S

1.) Establish an immediate federal mandate to supersede all state mandates that now require compulsory immunizations. (As Dr. Gordon Stewart said on the recent MacNeil Lehrer show --- only behind the "Iron Curtain" is anything mandatory.

2.) Place an immediate moratorium on the use of all pertussis vaccine.

3.) Dismiss all present government vaccine officials from the responsibility of regulating and releasing vaccines.

4.) Replace these officials with scientists with a track record of integrity.

5.) Remove the two year statute of limitations for legal action against the federal government and create a law that will permit legal action against government employees, if a law like that doesn't now exist.

6.) Demand full disclosure of the UCLA study and enforce an immediate follow-up of those in that study who suffered severe reactions. An independent group should be in charge of this follow-up and the findings of this investigation must be made public. I hereby volunteer myself to be a part of that non-governmental, independent group.

7.) A mandate that will require "all" healthcare providers to record the manufacturers' name and lot number of the vaccines administered, onto the medical records of all vaccine recipients.

Mrs. Anthony Ciotoli
Mr. Anthony Ciotoli
107 Pine Knoll Road
Endicott, New York, 13760

To Senator Paula Hawkins:

I am Mrs. Janet Ciotoli from Endicott, N.Y. My husband and I have personally attended two meetings pertaining to the controversy involving vaccines (topic: Pertussis vaccines) on 4126183 FDA Dept., Rockville, Maryland and 7/22/83 committee on Labor and Human Resources Hearing on Pertussis Task Force Report. We wish this to be entered as written personal testimony to be included with the written statements given at the meeting of the Pertussis Task Force Report held on 7/22/83. At this time, I represent my husband Anthony, our 5½ year old son Ryan, each of our families and the people who have been affected by what has prompted the writing of this testimony. Most important, we represent our son, Richard Anthony Ciotoli, who died 1/13/83 following his first DPT-oral polio vaccination at 2 months of age. His death certificate states his death due to: Irreversible shock due to Probable DPT Reaction. The purpose of our testimony is to tell what happened to our son-to convey to this committee just one statistic representing an adverse reaction to a vaccine represents. It is agreed that vaccines throughout the years have saved lives, but to remain open-minded on the subject of vaccines: benefits vs. risks, you must not close your eyes to the children and families who have, for years, suffered from the adverse affects of vaccines. We hope to convey to you also in our testimony, some sense of human morality which lacks in discussing statistics ans costs pertaining to this issue. Our testimony isn't a "formal structure" as the testimony presented at the meetings we've attended. Although our son has become a statistic in the eyes of many government departments, we cannot allow this to happen as we of him in our testimony.

Presently, I am employed as a part-time nurse on a Neurology-Orthopedic Unit and have been for almost 5 years. We had our first child while still attending nursing school. We clearly remember when he was receiving his DPT vaccination and how scared we were when he became ill shortly after receiving each one. Being parents for the first time, his symptoms alarmed us. No one had told us that vaccines couls react in such a way on a child. The pediatrician assured us that this was a "normal" reaction and "happened frequently". Each and every time our first child received his DPT vaccination, this "normal" "acceptable" reaction occured. Never was a family history reviewed or discussed, even though our family history includes epilepsy, deafness and blindness caused by unexplained neurologic damage, Bels Palsey, Rheumatic heart, allergies and diabetes.

Our second child was born on Nov. 9, 1983. The instant he was born we anxiously waited for the doctor to tell us we had a healthy baby boy. We felt that wonderful, overwhelming relief that most parents feel- that our baby was healthy!From that point on, it was now our responsibility as parents to make sure that our child would continue to grow healthy and strong.

On Jan.13, 1983, Richie was taken for his routine monthly examination. At that time, he was given his first DPT-oral polio vaccination. There was no such "recommended discussion" on benefits

vs. risks, pertaining to the vaccine, between parents and doctor. The vaccine was plain and simply given without worthwhile benefit of discussion. Shortly thereafter, Richie displayed similar symptoms as ourfirst child had done, 5 years befor, following his vaccination. Little did we know, as we do now, that both our children had and were suffering serious side reactions to the DPT vaccine. We had no idea of the deep and fatal trouble our son was in. Not even when we called the pediatrician who was on-call, 5 minutes before our son's last breath, explaining his symptoms since having his vaccination, was there great concern or alarm on the pediatrician's behalf. He felt it was unnecessary to personally meet us at the hospital emergency room where we decided to take Richie to be examined. The minutes that followed were our son's last. The ambulance was en route as I administered CPR to our lifeless child. My husband and our 5½ year old son watched, paralyzed, as I tried desperately to give life back to our child. My attempts failed, as did emergency room personnel who did everything possible without medical means.

The weeks that followed only added to the extent of our loss. The realization that a medical society which we had entrusted the health of our children to refused to "get involved" or fund the answers to our son's death. We had no choice but to find the answers ourselves which brought us to the meeting held in Rockville, Maryland on 4/26/83, after doing months of our own research.

The death of one of your own children is a long feared nightmare of every loving parent. It is not an easy or understandable death in any society, since children are expected to far outlive a parent. The added tradgedy to our son's death is that as loving and responsible parents, we have always believed in providing our children very opportunity to grow up healthy and strong. We took the recommended responsibility to make sure our children were vaccinated, yet who, WHO took the recommended responsibility to educate us? The system gives the doctors the right to choose whether or not to educate a parent, yet in turn, a doctor will deny the parent the right to know the risks as well as the benefits! The system has carelessly neglected the parents and given a group of professionalsthe power to "play God", denying the rights of all parents and especially the innocent victims...OUR CHILDREN! Why did our being uninformed of the risks and controdictions to vaccines have to happen after our son was dead?

We wish not to end our testimony with a question. We would like to thank you for taking the time to read our testimony and hope that our purpose of this testimony is clearly seen. It is not our intention to "scare" other parents, only to encourage that the public has a right to be educated. We believe in vaccinating children in an acceptable vaccine program which includes a safer vaccine and mandatory education program for parents. Personally, we feel that the vaccination program at present leaves much to be improved upon and is not acceptable to us nor to many of the families we represent. It is also our hope that our son will not only appear to you as a statistic but as a fatality due to an inadequate current system.

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ACTION HCRE-00

INFO OCT-00 COPY-01 ADS 00 EB-08 FA-12 H-01 STR-14
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INFO AMEMBASSY SINGAPORE
AMCONSUL HONG KONG
AMCONSUL OSAKA KOBE
AMEMBASSY SEOUL

UNCLAS SECTION 01 OF 02 TOKYO 16742

USDOC FOR ITA/IEP/FAP/OJ/4410/SMITH;
STATE PASS DHHS FOR FDA; USTR FOR ABELSON
E PASS SENATOR HAWKINS (FLORIDA)

E.O. 12356: NA
TAGS: BEXP, ETRD OREP, BTRA, TBIO, USTR, JA
SUBJECT: SEN. HAWKINS ASKS AND GETS JAPAN'S COOPERATION WITH VACCINE AGAINST DIPTHERIA, PERTUSSIS, AND TETANUS

REF: TOKYO 15619

1. SUMMARY. SENATOR HAWKINS RAISED HEALTH COOPERATION AND TRADE ISSUES DURING A 60 MIN. MEETING WITH JAPANESE MINISTRY OF HEALTH AND WELFARE (MHW) OFFICIALS ON TUESDAY MORNING AUG 9. MHW TOOK A COOPERATIVE ATTITUDE AND HAS NOW FOLLOWED-UP WITH ADDITIONAL INFORMATION FOR SEN. HAWKINS. ACTION REQUESTED: PASS INFORMATION TO SEN. HAWKINS. END SUMMARY.

2. AS A MEMBER OF THE U.S. SENATE LABOR AND HUMAN RESOURCES COMMITTEE SEN. HAWKINS IS INTERESTED IN A

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RECENTLY-APPROVED JAPANESE VACCINE AGAINST DPT (DIPTHERIA PERTUSSIS TETANUS) WHICH HAS A PROMISING SAFETY RECORD. SEE WAS TOLD BY U.S. FDA OFFICIALS IN WASHINGTON THAT JAPANESE OFFICIALS WERE HOLDING UP THE EXPORT OF THIS VACCINE DUE TO FEARS OF POTENTIAL LIABILITY FOR ADVERSE REACTIONS EXPERIENCED IN THE U.S. SHE TOOK THE OPPORTUNITY OF HER VISIT TO JAPAN TO CALL ON THE AUTHORITIES AT THE MINISTRY OF HEALTH AND WELFARE (MHW) TO LEARN THEIR VIEWS.

3. MHW OFFICIALS, KIYOSEI NAITO, DIRECTOR, INTERNATIONAL AFFAIRS DIV. MICHIHARA ABE, DEPUTY DIRECTOR, INTERNATIONAL AFFAIRS DIV. AND TOSHIHIKO HIRABAYASHI, DEPUTY DIRECTOR, BIOLOGICS AND ANTIBIOTICS DIV., WERE NOT AWARE OF PREVIOUS FDA APPROACHES EITHER TO MHW OR TO PRIVATE JAPANESE DPT MANUFACTURERS; THEY PROMISED TO CHECK AND REPORT TO SENATOR HAWKINS THROUGH THE EMBASSY. SENATOR HAWKINS' OWN VISIT WAS THE FIRST OFFICIAL CONTACT FROM THE U S. GOVERNMENT KNOWN TO THEM ON THIS SUBJECT FURTHER JAPANESE OFFICIALS STATED NO OBJECTION TO EXPORT OF VACCINE PRODUCT ON CONDITIONS

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THAT 1) SUFFICIENT JAPANESE DOMESTIC SUPPLIES WERE AVAILABLE TO MEET JAPANESE DOMESTIC NEEDS,

--

AND 2) THAT ONE OF THE FOUR INDIVIDUAL JAPANESE COMPANIES MANUFACTURING THIS BIOLOGICAL PRODUCT WAS WILLING TO EXPORT IT

4. AFTER SEN HAWKINS VISIT, MHW INTERVIEWED: TAKEDA CHEMICAL INDUSTRY, JAPANESE HOLDER OF THE PATENT ON THE DPT VACCINE, AND ALSO JAPAN'S LARGEST PHARMACEUTICAL COMPANY

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JAPAN'S NATIONAL INSTITUTE OF HEALTH (JNIH)
—
AND THE ASSOCIATION OF BIOLOGICAL MANUFACTURERS OF JAPAN. BASED ON THIS INFORMATION, MHW ASKS THE EMBASSY TO REPORT THE FOLLOWING TO SENATOR HAWKINS:
—
A. TAKEDA OF JAPAN AND WYETH OF THE U.S. HAVE BEEN TALKING SINCE SUMMER 1982 ABOUT A LICENSE AGREEMENT WHICH IN RETURN FOR ROYALTY PAYMENTS WOULD ALLOW WYETH TO SELL TAKEDA'S PERTUSSIS VACCINE IN THE U.S. SOME OF THE FOLLOWING TOPICS HAVE BEEN DISCUSSED IN THESE NEGOTIATIONS: (1) TAKEDA WILL SUPPLY ITS PERTUSSIS VACCINE IN BULK TO WYETH THROUGH WYETH JAPAN FOR THE TIME BEING. (2) WYETH WILL COMBINE IT WITH ITS OWN DIPTHERIA / TETANUS PRODUCT TO FORM A FULL DPT VACCINE. (3) WYETH WILL FILE AN IND APPLICATION WITH USFDA IN SEPTEMBER 1983 TO STAPT U.S CLINICAL TRIALS. TAKEDA STATED TO MHW THAT BULK PRODUCT HAD ALREADY BEEN SHIPPED TO WYETH.
B. TAKEDA HAS NEVER BEEN CONTACTED OFFICIALLY BY USFDA CONCERNING DPT EXPORT TO THE U.S. DURING HIS MAY 1982 VISIT TO INSPECT TAKEDA'S FACTORY, DR. DARRELL T. LIU DID NOT REQUEST ANY PRODUCT SAMPLES OF THE DPT VACCINE.
—
C. IF THE U.S. GOVERNMENT OR FDA HAS FURTHER QUESTIONS ABOUT TAKEDA'S DPT VACCINE, TAKEDA ASKS THEY BE DIRECTED TO PRESIDENT KONOSUKE FUKAI, ASSOCIATION OF BIOLOGICAL MANUFACTURERS, 1-2 ICHIGAYA SADOHARA-CHO, SHINJUKU-KU, TOKYO.

D. MHW LEARNED OF OFFICICAL CONTACTS BY FDA ABOUT THE DPT VACCINE TO THE JAPANESE NIH, BEGINNING IN MARCH 1982. IN FEBRUARY 1983, DR. MYER OF FDA REQUESTED SAMPLES AND

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ACTION HCRE-00

INFO OCT-00 COPY-01 ADS-00 EB-08 EA-12 E-01 STR-14
FBS-06 /042 W
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P 291049Z AUG 83
FM AMEMBASSY TOKYO
TO USDOC WASHDC PRIORITY
SECSTATE WASHDC PRIORITY 6723
INFO AMEMBASSY SINGAPORE
AMCONSUL HONG KONG
AMCONSUL OSAKA KOBE
AMEMBASSY SEOUL

UNCLAS SECTION 02 OF 02 TOKYO 16742

USDOC FOR ITA/IEP/EAP/OJ/4410/SMITH;
STATE PASS DHHS FOR FDA USTR FOR ABELSON
H PASS SENATOR HAWKINS (FLORIDA)

E.O. 12356: NA
TAGS: BEXP ETRD, OREP, BTRA, TBIO, USTR, JA
SUBJECT: SEN. HAWKINS ASKS AND GETS JAPAN'S COOPERATION

PRESIDENT TOSHIRU SHISHIDO OF JNIH SUPPLIED WITHOUT CHARGE A TOTAL OF 180 VIALS OF DPT VACCINE (30 EACH FROM 6 MANUFACTURERS). THESE WERE SHIPPED TO FDA IN MAY 1983, ON CONDITION THEY NOT BE USED REPEAT NOT BE USED FOR CLINICAL TRIALS.

E. TAKEDA HAS BEEN RELUCTANT TO EXPORT THE PRODUCT IN QUESTION BECAUSE THE FIRM IS NOT IN A POSITION YET TO COPE WITH ANY PRODUCT LIABILITY COMPLAINTS OR SUITS FOR ANY POTENTIAL ADVERSE REACTIONS IN THE U.S.

5. NEAR THE CONCLUSION OF THIS VISIT, SENATOR HAWKINS NOTED THE PRESENCE OF ENDEMIC HEPATITIS AMONG THE

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JAPANESE POPULATION AND THAT THE U.S. HAS A SAFE AND EFFECTIVE VACCINE WHICH JAPANESE OFFICIALS DO NOT ALLOW TO BE IMPORTED INTO JAPAN. SEN. HAWKINS PROPOSED THAT BOTH U.S. AND JAPAN COOPERATE TO MEET EACH OTHERS' HEALTH NEEDS, RATHER THAN ALWAYS INSIST UPON DEVELOPING EVERY PRODUCT DOMESTICALLY. JAPANESE MHW OFFICIALS NOTED THE ATTRACTIVENESS OF THIS DIRECTION OF COOPERATION BUT OBSERVED THAT IT WOULD ALWAYS BE NECESSARY TO ASSURE DOMESTIC SUPPLIES OF SUCH MEDICAL PRODUCTS--A POLICY TAKEN BY THE U.S. AND ALL EUROPEAN NATIONS. THEY STATED.

6. EMBASSY TOKYO HAS AGREED TO TELEGRAPH SEN. HAWKINS INFORMATION PROVIDED BY MHW. MHW WILL ALSO SEND INFORMATION TO JAPANESE EMBASSY IN WASHDC TO ATTN OF MHW ATTACHE MIZUTA TO INSURE SPEED AND ACCURACY OF DELIVERY TO SENATOR HAWKINS.

7. ACTION REQUESTED: PLEASE PASS INFORMATION TO SENATOR HAWKINS.
MANSFIELD

UNIVERSITY OF GLASGOW

MECHAN PROFESSOR
GORDON T. STEWART, M.D.

RUCHILL HOSPITAL
GLASGOW G20 9NB
TEL: 041-946 7120

DEPARTMENT OF COMMUNITY MEDICINE

20th August 1982

Senator Paula Hawkins,
US Senate,
Washington DC, 20510.

For the attention of Mr. Jay Howell

Dear Senator Hawkins,

Pertussis Vaccine

Colleagues in America have sent me copies of statements and testimony before the Sub-committee on Investigations and General Oversight of the Committee on Labor and Human Resources of the United States Senate on May 7th 1982. These include a testimony by Dr. Vincent A. Fulginiti on behalf of the American Academy of Pediatrics and Dr. William H. Foege, Director of the Center for Disease Control and it is with regard to their statements that I am writing to you because they both refer to me by name. Dr. Fulginiti misquotes my data and misinterprets my views on pages 5 and 6 of his testimony. Dr. Foege quotes me correctly but incompletely on page 10 of his statement but accuses me wrongly on page 14 of attributing encephalopathy to pertussis vaccine without investigating other possible causes. The figures which he quotes in this regard are erroneous, although the estimate given of the frequency of encephalopathy is that which I calculated. Both he and Dr. Fulginiti refer only to one short publication by me in 1977, overlooking or ignoring other relevant studies published subsequently in Britain and in the United States.

Reference is also made to the programme by NBC/WRC TV broadcast in various parts of America, in which I appeared. It is alleged that this programme is "distorted, verging on the irresponsible" (Dr. Foege) and "biased and inaccurate" (Dr. Fulginiti). I have to say that I met with the television staff responsible for the programme on four occasions. There was no pressure upon me in any way to give anything other than my own personal opinion. They made every effort, as far as I was concerned, to examine an impressive volume of evidence and to research and present both sides of the case. Having seen the programme, I think it is unfair to accuse them of bias and sensationalism and to allege, as Dr. Foege does, that "attempts are being made to provoke a major controversy where one does not currently exist".

The testimonies to which I refer are by distinguished physicians representing organisations for which, from personal knowledge as well as repute, I have great respect. I regret having to raise objections but I can provide chapter and verse to support them if you so desire.

Yours sincerely,

Gordon T. Stewart.

UNIVERSITY OF GLASGOW

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DEPARTMENT OF COMMUNITY MEDICINE

9th December 1982

Senator Paula Hawkins,
United States Senate,
Committee on Labor and Human Resources,
Subcommittee on Investigations and
General Oversight,
Washington D.C. 20510,
United States of America,

Dear Senator Hawkins,

As requested in your letter of August 30th, I wrote to Ms. Terri Parker on October 25th enclosing data relating to your enquiry on Whooping Cough and Pertussis Vaccine. Having had no acknowledgement, I am wondering if you have received this letter and enclosures.

Meanwhile, I have received a full report of the Hearing of your Subcommittee. This was not available to me when I wrote and requires further comment because there are several serious errors of fact in references to the situation in Britain and, in particular, to the studies with which I was concerned. These errors stand in need of correction, as follows:

Dr. Foege (p.19): these and other assessments by CDC personnel (see MMWR Dec 3, 1982) and by your respondents (e.g. Dr. Fulginiti P.105) of events in Britain are based upon unvalidated notifications which are manifestly fallacious, especially since 1975. There is good evidence that substantial parts of the outbreaks reported in Britain in 1978-79 and 1982 were attributable to infections other than whooping cough, although there was a considerable rise in that also, on schedule with the expected 44-month cyclical recurrent pattern.

Deaths in Britain, as in USA, have decreased steadily since about 1900. The bulk of the decrease (over 90%) occurred by 1950, before there was any appreciable use of pertussis vaccine. The decrease has continued since then. Deaths in the period since 1975 (when vaccine acceptance fell to below 50%) have continued to decrease. So also, in many parts of the country, have admissions to hospital, e.g. to less than 1% of validated cases in metropolitan Surrey which has a much larger proportion of young children than most other populous areas in Britain. (Table 1 appended).

(p.22): this is a very incomplete account of my preliminary study in 1977 which described 65 , not five cases of encephalopathy. There is no reference to more detailed studies reported in 1978 (in USA) and 1980 in which it is shown that the gradient of severity of adverse effects of pertussis vaccine is such that many cases are not recognised immediately. Impressions based only upon acute cases referred to hospital under-estimate the frequency of brain damage. This same criticism applies to Dr. Foege's description of the National Childhood Encephalopathy Study which was by design restricted to acute cases. Even so, it showed a highly significant increase in adverse neurotoxic reactions in children who had received pertussis-containing vaccines (DPT) during the preceiding 72 hours, as compared with controls or with children receiving other vaccines.

Continued.....

(p.23): The "estimated frequency" of brain damage (1:10,000 cases) and death (1:1,000 cases) associated with pertussis infection is likewise questionable. In Britain, as in USA, the few deaths associated nowadays with pertussis occur mainly in infants below the age for completion of vaccination. Brain damage is very rare. Even in the National Childhood Encephalopathy Study which by definition included acute cases occurring after pertussis, the estimated frequency was only 1:300,000 (p.114 of their report). But I agree with Dr. Foege that the relative risks must be assessed, so I am appending estimates based upon recent data in Britain (Table 1).

(p.23): SIDS. Systematic studies to date have shown no significant relationship between SIDS and immunization but it is impossible to exclude the possibility of a connection because there are well-documented reports in USA and Britain of sudden, unexplained deaths immediately after injection of pertussis-containing vaccines and this is not true of other vaccines. // Fuller investigation is required, particularly in view of the identification of highly toxic components in pertussis vaccine and the lack of any reliable test for these in current standardization procedures.

(p.34): The "Hard core of unimmunized children" need to be looked at in more ways than one. The obvious question is whether or not they show increased frequency of whooping cough. Dr. Hinman makes no reference to this. In Britain, with 50% or more of infants not vaccinated against pertussis, the current frequency of infection and of hospital admissions is not excessive. In Glasgow, the severity of disease is manifestly diminishing (Table 2).

(p.36): Your own statement that there is "an understatement of adverse reaction rates" is itself an understatement. The controversy which we all deplore would diminish if Drs. Foege, Hinman, Meyer and others who offered advice to you would admit their uncertainty and stop referring to unrepresentative figures from Britain and elsewhere which over-estimate the prevalence and risks of whooping cough and under-estimate the risks of pertussis vaccine.

(pp.90-95): Reprint of paper in the New England Journal of Medicine on Pertussis Vaccine - an analysis of benefits, risks and costs. The analytical model in this well-written article by workers from CDC and Harvard School of Public Health is based, unfortunately, upon obsolete data and projections which are disproved by events in Britain, West Germany and Sweden. I have offered current, verifiable data for testing in the same model but this offer has been refused by the Journal and ignored by CDC.

Control of pertussis in USA may be less complete than they claim. Table 2 (appended) shows that there is a much higher hospital admission rate for cases of pertussis detected in surveys by CDC in USA than in surveys in Britain. This can only mean that the much larger proportion of cases which do not require admission to hospital isundetected and that pertussis vaccine, in USA as in Britain, is not so effective in promoting herd immunity as is claimed.

(pp.99-119): The above criticisms are applicable also to statements by Dr. Fulginiti and others. It is certainly wrong for critics of vaccination to overstate dangers but it is no less wrong for medical men and health authorities to give unqualified reassurances about its safety and to overstate the risks of disease, especially when they are referring to hypothetical situations, hearsay evidence and unvalidated data.

Continued.....

I realise that most of what I am saying here is critical of views expressed to your Committee by respected and well-qualified persons and organisations. Unfortunately, in the climate of debate about pertussis, I know of no other way to be helpful and this is true in Britain no less than in USA. As I read the situation, the Health Authorities, guided by the medical establishment and pharmaceutical firms in both countries and internationally, have overlooked remediable defects and dangers in pertussis vaccine and in their surveillance of vaccination programmes for about 20 years. Together with the Editors of major journals, they have also ignored factual data and resisted legitimate, informed criticism within professional circles, with the inevitable conseqwuence that timely corrective action was impeded.

There is one other aspect of the problem which, I imagine, your Subcommittee will not wish to overlook. Vaccine acceptance in USA is very high indeed because of the regulations which, in most states, require full schedules of various vaccinations before children can be admitted to public schools. As I read this regulation, the denial of any option on medical grounds is contrary to the spirit of the American Constitution, to the rights of parents and to the human rights of children. In the case of pertussis, a degree of compulsory vaccination is also medically unsound because it presumes certainty about the safety and efficacy in the face of visible evidence to the contrary.

Your Subcommittee is performing a most valuable service in opening up the subject for informed debate and it is obvious that corrective action can now be contemplated with much less anguish. I count it a privilege to contribute and I am grateful to you for enabling me to do so.

Yours sincerely,

G.T. Stewart.

Gordon T. Stewart

Enc.

TABLE 1: Surveillance of Whooping Cough in Britain and USA

Data obtained in	BRITAIN 1978 - 1979			1978 - 80	USA 1978 - 81
Location and reference	Glamorgan(9)	Guildford(10)	Glasgow(11)	21 Areas*(12)	42 States*(28)
Children at risk (% of total population)	72,300 (20%)	57,700 (42%)	236,700 (23%)	437,758 (+)	50,000,000 (estimate
No. of cases (per 1,000 children)	2,295 (32)	658 (11)	3,150 (13)	11,776 (27)	1,277 (0.026)
" " " <1 year of age (%)	243 (11)	+	358 (11)	70(0.6)	791 (62)
" " " adm. to hospital (%)	64 (3)	5 (0.8)	240 (8)	171 (1.5)	740 (60)
" " " with encephalopathy (%)	2 (0.1)	0	0	+	5 (0.4)
" " deaths (per 1,000)	3 (1.3)	0	0	+	7 (0.6)
Bacteriological confirmation	39%	33%	33% §	25%	72% §
Secondary attack rate (household)	41%	36%	37%	50%	+
Vaccine acceptance (DTP≥3)	50%	43%	56%	57%	95%
Vaccine protection-contacts 1-5 years	59%	53%	51%	59%	82%

*Surveillance by PHLS in 21 areas (Britain) and by CDC (USA). PHLS figures refer to balanced group of children aged 0 - 6 receiving DTP x 3 or DT x 3.

+ Not stated

§ Mainly in cases admitted to hospital

Gerald Hawkins 9/12/82

Table 2: Notifications, admissions to hospital and deaths attributed to whooping cough in Scotland and in hospitals in Glasgow.

Period	SCOTLAND			GLASGOW HOSPITALS				
	Notifications No. (per 1,000)	Hospital admissions No. (per 1,000)	Deaths No. (per 1,000)	Hospital admissions (% of total) < 1 year	Others	Deaths No.	No. of children vaccinated * Glasgow %	Scotland No. & %*
1950-54	79,971 (12.6)	N.A.	250 (0.04)	498(32%)	1,064	54	N.A.	Unknown
1955-59	33,792 (5.1)	N.A.	57 (0.008)	417(41%)	589	12	N.A.	Unknown
1960-64	19,036 (2.9)	2,447 (0.37)	23 (6.009)	536(50%)	539	7		381,350 (78%)
1965-69	7,956 (1.2)	1,325 (0.20)	14 (0.002)	276 (53%)	246	2		361,851 (77%)
1970-74	6,833 (1.0)	1,223 (0.18)	12 (0.002)	253 (67%)	124	4	69	320,132 (80%)
1975-79	7,512 (1.2)	1,382 (0.22)	5 (0.0008)	123 (48%)	135	0	49+	181,842 (50%)

N.A. = Not Available

( ) = per 1,000 children (<15 years) per year

* i.e. receiving DTP x 3 as % of children born during period.

+= estimates

Sources of Data: CSA, RG(S), MOH Reports, Glasgow 1950-72, GGHB.

GLASGOW 1980 - 82:

		Notifications	Admissions
1980		157	29
1981		223	47
(Jan-Oct)	1982	677	70

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WHOOPING COUGH IN THE UNITED STATES AND BRITAIN

To the Editor: A 1978 editorial in the *Journal* expressed "reasonable doubt" about pertussis vaccine.[1] One reason for doubt was the absence of reliable data about the prevalence and pattern of whooping cough. This gap is now filled by a supplementary survey reported by the Centers for Disease Control in Atlanta.[2] For the first time since about 1950, the data provide a broad enough base for comparison with the British data referred to in the editorial and in other issues of the *Journal*.

Comparison of the data from the Centers for Disease Control with those from three independent surveys[3-5] in Britain, separately or pooled, shows major discrepancies (Table 1). Whooping cough is apparently much less prevalent in the United States but much more severe as judged by the larger numbers of infants affected, of hospital admissions, of cases of encephalopathy, and of deaths.

The data from the Centers for Disease Control are inconsistent with the recent experience in Britain,[6-9] where whooping cough has been prevalent but seldom severe, and vaccination has been less effective than in the United States. Even if vaccination in the United States is more efficacious (82.4 per cent, as claimed), application of British rates and ratios to the U.S. population suggests that the overall attack rate would be at least 9 per 1000 children, of whom about 120,000 would be four years of age or younger. Most of these cases would be mild, self-limiting infections, as they are in Britain, but severe cases would undoubtedly occur. I suggest that these are the cases detected in the survey conducted by the Centers for Disease Control.

Whooping cough has recurred cyclically (every 44 months), as expected, in Britain. Repeated references have been made in the United States to this outbreak, which is said to be the largest since 1957.[9] The fact is that it is subsiding and is clearly visible, once again, as an outbreak of notifications, an unknown proportion of which are cases of whooping cough. The true figure, as shown by hospital admissions, bacteriologic tests, and the low returns from the research unit of the Royal College of General Practitioners and from many populous areas, is far short of the alarming number claimed by the British government and echoed by the Centers for Disease Control. Severe cases are uncommon, and deaths remain rare indeed. In most areas the majority of young children have not received the diphtheria–pertussis–tetanus vaccine.

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Table 1. Comparison of Data on Whooping Cough in the United States and the United Kingdom.*

	United States (1978–81)	United Kingdom (1978–79)			
	48 states	Glasgow[3]	Guilford[4]	Glasgow[5]	Total[5]
No. of cases	1277	2295	658	3130	6103
Below 1 yr of age (%)	791 (62)	243 (11)	—	358 (11)	
Hospitalized (%)	740 (60)	64 (3)	5 (0.8)	240 (8)	309 (5)
With encephalopathy (%)	5 (0.4)	2 (0.1)	0	0	2 (0.03)
Resulting in death (%)	7 (0.6)	3 (0.13)	0	0	3 (0.05)
Attack rate/1000 children/yr	0.0065	16	5.5	6.3	6.5
Secondary attack rate	NA	41%	36%	37%	38%
Vaccine protection (1–5 yr)	82.4%	49%	53%	43%	47%
Bacteriologic confirmation †	72%	39%	33%	33%	33%

(Excerpt From British Medical Journal, Vol. 287, 23 July 1983)
(p.287)

Whooping Cough and Pertussis Vaccine

SIR,—The comments made by Miller and Ross[1 2] and others[3 4] in your columns about the whooping cough and pertussis vaccine controversy in general and myself in particular can be answered only by examining verifiable epidemiological data and reliable clinical reports. Either without the other is liable to be misleading.

The relevant period is from 1970 to 1982. Before 1970 it was agreed, even in your columns,[5 6] that pertussis vaccine was "not very effective," in the words of the summary of a comprehensive national survey. After that, some people claimed[7] that the vaccines were more effective because antigens 1-3 were included, but this claim, unconfirmed epidemiologically and refuted microbiologically,[8] was not supported by the international expert panel of the World Health Organisation[9] nor by one of the main manufacturers,[10] who pointed out that these antigens had been included in their vaccine since 1964. Anyway, there was an extensive outbreak in 1970-1, with 51 deaths. Nothing was published between 1970 and 1974 to show that the vaccine was more effective, but there was growing concern about its safety to such an extent that by 1975 acceptance had dropped to less than 50% of eligible infants in most parts of Britain. There has been little change since then. About half of the children born in Britain since 1974 have not received pertussis vaccine, so that the child population is naturally divided into two halves in which the incidence and risks of whooping cough and the incidence of adverse reactions to pertussis vaccine and its efficacy can be compared.

Between 1969 and 1978 available data consisted mainly of notifications,[11-13] but since then there have been several prospective surveys in Britain[14-19] and two retrospective ones in the United States[20 21] of whooping cough and its complications. Unfortunately, the same cannot be said of adverse effects of the vaccine, but it is possible, from data in the National Childhood Encephalopathy Study[22] and various other sources,[23-31] to estimate the incidence of severe toxic effects and hence to compare benefit with risk.

Table I summarises the data from these surveys. The four British surveys show broadly similar rates of vaccine acceptance, of secondary attack in household contacts of known cases, and of vaccine protection calculated from this. Most cases were in children older than 1 year. In the group aged 1-5 years the efficacy of pertussis vaccine was only 51-59%. Admissions to hospital were infrequent (0·6-8% of cases), as were deaths and encephalopathy.

The American surveys show, in contrast, a seemingly high attack rate (62-76%) in infants and much higher rates of death, encephalopathy (0·4-1·3%), and admission to hospital (57-60%). The general attack rate appears to be much lower, but this is because the American surveys were

restricted to babies and young children admitted to hospital.[22] Vaccine protection is claimed to be about 82% (63-94%), which equates to the rate claimed in Britain if reliance is placed on notifications.[11-14] In other studies of household contacts in the United States[23 24] the protection rate is much lower, as in Britain, although vaccine acceptance is about 95%. It is possible[21] that the booster injections of vaccine given in the United States afford clinical protection to older children, but the high incidence of infections in infants throws doubt on the notion that herd immunity is thereby obtained since infants seldom contract infection except from older children, who are missing in both US surveys.

These data, all of which are verifiable, provide a basis for estimating risk-benefit by converting rates to prior probabilities and comparing the risks of disease with those of pertussis vaccine, as calculated from various sources,[20-21] including the National Childhood Encephalopathy Study.[22] It is important to realise, as Miller and Ross pointed out,[2] that the estimate of attributable risk provided by the national childhood encephalopathy study is epidemiologically satisfying because controls are available for the cases notified by hospitals. But, equally, by no means all children reacting to vaccines are referred to hospital,[20] and in detecting rare events such as encephalopathy epidemiology is an inadequate instrument unless attention is paid also to relative incidences of relevant occurrences. There is no doubt that, in this respect, pertussis vaccine has a consistent record in the published work and in unpublished reports since 1933 of neurotoxic and other severe sequelae unmatched by any other vaccine, long before there was any adverse publicity about it in the media.

Since about 1950 the risk of death or of severe disease from whooping cough has been confined essentially to infants. Comparison of risks (table II) shows that if an infant contracts whooping cough (1:14-1:100) its risk of severe disease as indicated by admission to hospital (about 1:300-1:3000) is not very different from its risk (1:750-1:3000) of a severe reaction after pertussis vaccine. The average risk of encephalopathy with permanent brain damage after whooping cough (1:38 000) is within the range (1:25 000-1:110 000) of that reported after diphtheria, pertussis, and tetanus vaccination. The risk of death (1:130 000) after whooping cough (mainly unconfirmed) is not too different from that reported (1:100 000), although also unconfirmed, after pertussis vaccine in 1979-80.

On a population basis, the risk of any child contracting infection (1:14-1:100) varies considerably from time to time between persons and between and within places. About 25-35% of those who develop whooping cough have already received three infections of diphtheria, pertussis, and tetanus vaccine and, in older children, the proportion is higher.[15 16] Encephalopathy with permanent brain damage after diphtheria, pertussis, and tetanus vaccine is variously estimated at 1:17 000-1:178 000,[22 25 27 29 30 31 34] which is higher than that detected after whooping cough (1:300 000) in the National Childhood Encephalopathy Study.[22]

TABLE II—*Estimates of risks of whooping cough and pertussis vaccine based on incidences of reported occurrences (numerator = number of occurrences reduced to unity; denominator = corresponding number of children at risk by age groups)*

Incidence	Age (yrs)	High risk areas	Low risk areas	Averages*
Whooping cough	0–15	1:32	1:100	1:60 (1:100)
	1– 4	1:16	1:50	1:27 (1:80)
	0– 1	1:14	1:100	1:40 (1:117)
Admission to hospital	1– 1	1:336	1:3060	1:547
Permanent brain damage	0– 1	1:2000	0	1:38 000 (NCES[22] 1:300 000)
Death	0– 1	1:1300	0	1:12 600
	0–15	1:34 000	0	1:130 000)
England and Wales	0–15			(1:540 000)
Scotland	0–15			(1:260 000)
All causes	0– 1			(1:36)
After pertussis vaccine	0– 2	CSM (1979-80)		(1:100 000)
After all other vaccines	0– 2	CSM (1979-80)		(1:450 000)
Permanent brain damage after pertussis vaccine	0– 2	Britain[17 18 21]		1:17 000-1:54 000
	0– 2	DHSS tribunals		(1:25 000)
	0– 2	"		(NCES[22] 1:110 000)
	0– 2	West Germany[20]		1:80 000
	0– 2	Prensky[31]		1:178 000
Neurotoxic reactions	0– 3	Britain, USA, Holland[21 27]		Range 1:750-1:3000
Systemic reactions		Britain, USA, Holland[21 28]		Range 1:2 -1:10

*From surveillance of 1978-9 outbreak in Britain/Glamorgan[16] is taken as a high risk area, Guildford[17] as a low risk area.
Estimates in brackets are calculated from notifications to OPCS Registrars General, or DHSS (Tribunals, NCES).
OPCS = Office of Population Censuses and Surveys. CSM = Committee on Safety of Medicines.
DHSS = Department of Health and Social Security. NCES = National Childhood Encephalopathy Study.

It is also higher than the risk of permanent lung damage reported in other surveys.[26 28]

Clinical reports from various sources show that in the outbreaks of whooping cough in the 70s (1970-1, 1974-5, 1978-9) and in 1982 many babies with severe infections were admitted to hospital, confirming the fact also apparent in the American survey that current vaccination programmes do not necessarily protect infants. The death rate, however, has fallen steadily during this time. In 1982, only 14 deaths were certified in Britain and in these, as in all deaths since 1964, most were in infants below 6 months of age or vulnerable in other ways. Only two were confirmed bacteriologically (only 4% since 1964), but other pathogens (parainfluenza and respiratory syncytial viruses, *Pseudomonas* spp) were isolated from four. In the 1982 outbreak there was a considerable overlap between notifications of whooping cough and various respiratory viral infections, as in 1977-9.[18] Continuous surveillance of whooping cough, among other infections of childhood, in Glasgow since 1974 shows that outbreaks and severity are much more intense in areas of stress and deprivation, where spread of infection within and beyond households is expedited by large numbers of children in crowded homes, playgroups, and schools.

All of this goes to show that whooping cough may be almost as prevalent now as in the 1960s in some parts of Britain and, apparently, in the United States. It is still a distressing disease, a threat to life in some infants, and a problem badly in need of resolute attack in the clinical, epidemiological, and public health sectors. There is good reason in the data to believe that if deprivation and overcrowding can be abated the incidence and severity of the disease will diminish, but until this happens a vaccine is needed. The data show that the present vaccine does not control outbreaks. I believe that it is insufficiently effective and too risky to be used in mass vaccination programmes, although I would agree that it should be available to parents and doctors who want to use it so long as they are advised of its limitations. This constraint should be applied also to international programmes and no fault compensation introduced for victims of adverse reactions.

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21 Pertussis vaccination: the present position. *Med Advis Comm Br Paediatr Assoc* 1981;283:1595-8.

TABLE I—*Surveillance of whooping cough in Britain and USA*

	Britain				USA	
	1978-9	1978-9	1978-9	1978-80	1978-81	1982
	Glamorgan[16]	Guildford[17]	Glasgow[18]	21 areas*[19]	62 States[23]	Maryland[24]
Children at risk (% of total population)	72 300 (20%)	57 700 (42%)	236 700 (23%)	437 758(1)	50 000 000 (estimate)	†
No of cases (per 1000 children)	2 295 (32)	658 (11)	3 150 (13)	11 776(27)	1 277 (0·026)	795
No of cases <1 year of age (% of cases)	243 (11)	†	358 (11)	70 (0·6)	791 (62)	60 (76)
No of cases admitted to hospital (% of cases)	(64 (3)	5 (0·8)	240 (8)	171 (1·5)	760 (60)	45 (57)
No of cases with encephalopathy (% of cases)	2 (0·1)	0	0	†	5 (0·4)	1 (1·3)
No of deaths	3 (0·13)	0	0	†	7 (0·55)	0
Bacteriological confirmation	39%	33%	33%‡	25%	72%‡	54%
Secondary attack rate (household)	41%	36%	37%	50%	†	††
Vaccine acceptance (diptheria, tetanus, and pertussis vaccine three times)	50%	43%	56%	57%	95%	89—86%
Vaccine protection-contacts 1-5 years	59%	53%	51%	99%	†	†

*Surveillance of 21 areas by the Public Health Laboratory Service of balanced groups of children aged 0-6 receiving diphtheria, tetanus, and pertussis vaccine three times or diphtheria and tetanus vaccine three times.
†Not shown.
‡Mainly in cases admitted to hospital.
††Three out of four cases had received diphtheria, tetanus, and pertussis vaccine three times.

DISSATISFIED PARENTS TOGETHER

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This is a statement of the purposes and policies of Dissatisfied Parents Together (DPT). Our reason for organizing stems from a common concern for the health and well-being of all children. The following is a statement of our specific goals related to pertussis and the pertussis vaccine:

* To effect in-depth research and a comprehensive study of the side effects and effectiveness of the pertussis portion of the DPT vaccine.

* To effect mandatory reporting by physicians, and to encourage voluntary reporting by parents of adverse reactions to the DPT vaccine to a central recordkeeping agency.

* To promote better education among physicians and parents as to the possible side effects of the pertussis vaccine and as to the dangers of pertussis itself.

* To identify children who are at high risk of having serious adverse reactions to the vaccine.

* To effect the development of a safer vaccine.

* To promote public debate on whether or not the pertussis vaccine should ever be a mandatory requirement to attend school.

* To promote the adoption of a compensation program for persons who have been retarded or seriously disabled by the pertussis vaccine.

* To assure the availability of adequate treatment and social service programs for persons who have been damaged by the pertussis vaccine.

PERTUSSIS AND PERTUSSIS VACCINE: Information for Parents — Part One

Introduction

The following information is the first part of a more comprehensive parent information guide that the volunteer staff of Dissatisfied Parents Together is preparing for parents. This information is based on ten months of research and review of scientific and medical literature on pertussis and the pertussis vaccine. In addition, we have had numerous discussions with physicians, parents and health officials. The information in this booklet is intended to assist you, as parents, to be better informed so you can more effectively protect the health of your children. It has not been written by physicians and is not intended to be medical advice. It neither recommends, nor opposes pertussis vaccination. Whether or not to vaccinate a child against pertussis (whooping cough) is a decision which you, as parents, must make in consultation with physicians and in consideration of the laws of your state. Each case should be evaluated individually with the benefit of the best medical advice you can obtain.

The purpose of this guide is to help you identify questions which you may want to ask your physician about pertussis and the pertussis vaccine as well as identify additional sources of information you may want to consult to further your knowledge about this issue. If, after discussing this subject with your physician, you do not feel your questions are being answered to your satisfaction, you may wish to consider talking them over with another doctor.

Normally, the pertussis vaccine is given to children in the United States at 2, 4, 6 and 18 months, and between 4 and 6 years of age in combination with a vaccine for diptheria and one for tetanus. The shots are referred to as the "DPT" or "DTP" series of shots. There has been little or no controversy about the effectiveness and safety of the diptheria ("D") and tetanus ("T") portions of the DPT vaccine. Therefore, this information focuses on the "P" or pertussis portion of the DPT shot. While these three vaccines are usually administered together in one shot, it is possible in appropriate cases discussed later, for children to receive only the DT vaccines without the "P" portion, or with a partial dose of pertussis vaccine given separately.

PERTUSSIS (Whooping Cough)

Before discussing the pertussis vaccine, it is important for parents to understand that pertussis disease (commonly known as whooping cough) can be very serious, particularly for young infants. In 1934, as many as 260,000 cases of pertussis were reported in the U.S., including 7,000 deaths. Newborn babies and young children, whose small bodies were not yet strong enough to withstand the prolonged coughing and vomiting caused by the disease, often died. And because there were no antibiotics at that time, there were no means to control the secondary complications of pneumonia, bronchitis and otitis media (ear infection) that often accompanied the disease.

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During the last ten years, the Centers for Disease Control estimate approximately 1,000 to 3,000 cases of whooping cough and 5 to 15 deaths due to pertussis have been reported each year in the U.S. A recent health bulletin summarized the continuing dangers of pertussis as follows:

> In its early stages, pertussis is indistinguishable from the many colds common to children. However, after one to two weeks, the illness gets progressively worse. Thick mucous builds up in the lungs, triggering severe coughing spells as children try to clear their clogged-up airways. Children can cough so long and hard that they literally cannot "catch their breath"; their faces turn blue when they are unable to get fresh oxygen into their system. As the coughing spell ends, children gasp for their next breath with a characteristic crowing sound, or whoop. These coughing spells can occur up to 40 times a day and can last two to three months.
>
> There is no effective antibiotic treatment for pertussis. Prolonged hospitalization is necessary in many cases to provide respiratory support and intravenous nutrition. Permanent lung disease, seizures, brain damage and death can result from whooping cough and its complications. Younger children, because of their smaller air passages, are more at risk for the problems produced by pertussis infection. The fatality rate is especially high in infants under six months of age.[1]

Because whooping cough is highly contagious, most states in America have passed laws and adopted regulations requiring children to have a series of 3 to 5 DPT shots before they can enter school. Many states, however, permit parents to refuse to have their child vaccinated on the grounds of "personal conviction" or "philosophical objection". As of October, 1980, these states were California, Georgia, Idaho, Kansas, Louisiana, Maine, Michigan, Minnesota, Montana, Ohio, Oklahoma, Rhode Island, South Dakota, Utah, Vermont, Washington and Wisconsin. In addition, a child may be able to be exempted from the vaccine requirement if the parent can obtain a written statement from a physician stating that the vaccine would be detrimental to the child's health. Most states also will exempt a child from the vaccine requirement if the parent objects on the grounds of religious conviction.

The laws and regulations change from time to time, however. A later part of this paper discusses your legal rights and obligations and provides further information on how you can find out about the laws and rules in your state.

BEFORE YOUR CHILD RECEIVES A VACCINATION

Under certain circumstances, the pertussis vaccine is "contraindicated" (i.e., should not be given). It is vitally important for you, as parents, to make sure your child does not receive the pertussis vaccine if one of these contra-indications exists. There are several procedures which a cautious parent would insist upon before her child receives a vaccination, whether it be in a public health clinic or at a private pediatrician's office.

1. Make sure a doctor gives your child a careful physical exam before each DPT shot. This should include taking a temperature and a thorough exam of your child's throat and ears to make sure there is no infection present. Be sure to report any illness, however slight, that your child has had in the previous month. Mention any viral or bacterial infections that you or members of your family may currently have or that your child may have been exposed to. In general, physicians in the United States agree that "children with an acute febrile illness"(i.e., significant fever) should not be given the pertussis vaccine until they are fully recovered. However, there are some physicians who believe that the vaccine should be delayed if the child has any signs of illness, including a cold, and especially an upper respiratory infection, diarrhea or ear infection. The optimum time to give a child any vaccine is when the child is healthy.

2. The examing physician should take a detailed medical history of your child and your family before the child is vaccinated. Be sure to mention if your child or anyone in your family has a history of convulsions or neurologic disease. Although the U.S. Public Health Service and the American Academy of Pediatrics do not generally consider a personal or family history of convulsions or non-deteriorating neurologic disease to be a contraindication to the pertussis vaccine, your doctor may conclude that, in your child's case, pertussis vaccination is contraindicated. Many European countries including West Germany, England, the Netherlands and Sweden, consider that if a child or his immediate family has a history of seizures or other neurologic disease, then the pertussis vaccine should not be given to that child.

Throughout the scientific literature dealing with pertussis vaccine during the past 40 years, there have been reports by some researchers that a severe family history of allergies may pre-dispose a child to reacting to the pertussis vaccine. Although today a child with allergies or a family history of allergies is not recognized as a contraindication to the pertussis vaccine in either the U.S. or Europe, it is a good idea to let your physician know if your child or your family has a long history of severe allergies. It is also important to tell your doctor if any of your child's brothers or sisters have previously reacted severely to the DPT shots. If so, your child may be more likely to react severely.

3. Before your child receives the pertussis vaccine, you may want to ask your doctor to give you a copy of the vaccine manufacturer's package insert to read. Or you can ask for a copy of the PDR (Physicians' Desk Reference) section on the particular pertussis vaccine your child is to receive. This is the same as the manufacturer's package insert. In addition, you may want to ask your doctor to give you a copy of the part of the American Academy of Pediatrics'

Committee on Infectious Disease Red Book that deals with pertussis and pertussis vaccines. Read these carefully before your child receives the vaccine. If you do not understand something in these statements, ask your doctor to explain. These sources of information can help identify special circumstances under which pertussis vaccination should not be given or should be delayed.

4. If this is not your child's first DPT shot, be sure to notify your doctor of any reactions your child may have had to each of the earlier shots, including a severe local reaction such as extreme swelling, redness and pain at the site of the injection. Parents need to be aware of various definitions of severe reactions to the pertussis vaccine. Severe reactions are discussed more fully later in this guide and you should also discuss them with your physician. A severe reaction to any previous pertussis vaccination usually contraindicates the administration of further pertussis vaccine.

5. If your child is more than five years old, you may want to discuss with your doctor the risks of giving your child the pertussis vaccine versus the risks of whooping cough to a child this age. According to the federal Immunization Practices Advisory Committee, "routine immunization against pertussis is not recommended for those 7 years old and older."

6. If your infant has had a problem with breathing which could predispose the child to sudden infant death syndrome (SIDS), you may want to discuss with your doctor the comparative risks of administering the DPT vaccination before the child ceases to have breathing difficulties. If your child was born prematurely or is significantly underweight, you may want to discuss with your doctor the possibility of delaying pertussis vaccination until your child attains the normal weight for his or her age group. These are particularly difficult questions, because infants who were premature, underweight, suffer chronic illness or have serious breathing difficulties are also at high risk of serious complications from whooping cough.

7. You may want to discuss with your doctor possible precautions you can take to minimize the risks of your child having a serious reaction. A recent medical journal article written by researchers at the National Institutes of Health suggests that fever control agents (such as acetominophen or aspirin) and sweetened fruit juices may help to avoid the fever and low blood sugar which are sometimes associated with serious reactions. You may also want to remind your doctor of any drugs or medications which your child is taking (or has taken recently) and ask whether these drugs could increase the risk of severe reaction to pertussis vaccine.

8. Finally, you should know your legal rights and obligations concerning pertussis vaccination. Laws and regulations vary from state to state and even within counties of some states. Before having your child vaccinated with the pertussis vaccine, you may wish to ask your state or county health departments the following questions:

A. Is vaccination for pertussis legally required before my child may enter school? If so, how many shots are required? What flexibility does the law provide if a parent wants to defer the pertussis shots until the child is two years old or older? What is the legal consequence if my child does not get the required number of shots before he or she enters school?

B. Does the law say that a child does not have to be vaccinated if his parents have a "personal conviction" or "philosophic objection", i.e., if parents believe vaccination is not in the child's best interest? Does the law provide an exemption on the grounds of religious conviction?

C. What is the legal definition in your state or county of a "medical exemption" to the pertussis vaccine? What latitude is given to the physician's judgment as to whether or not the pertussis vaccine is medically contraindicated for a particular child?

In most states, if your child has had a recognized severe reaction to a previous DPT shot and you do not want him to receive more pertussis vaccine, you can legally refuse to allow the child to be injected with pertussis vaccine. If your physician is encouraging you to vaccinate your child in the face of a previous severe reaction, you may want to consider contacting another doctor for a second opinion. If you cannot find a doctor who you feel is sufficiently sensitive to your concerns, contact Dissatisfied Parents Together and we will attempt to help you locate one.

YOUR CHILD'S MEDICAL RECORDS

Before your child receives a DPT vaccination, it is not only important to make sure your physician has given your child an adequate physical examination, but it is also important that he enter the results of the exam in your child's medical records. Make sure your physician's evaluation of your child's physical and mental development up to the time of the vaccination is also entered on the chart.

Before your child is vaccinated, you should ask your physician to enter on his the chart the date and time of day the DPT vaccination is administered to your child, as well as the vaccine manufacturer's name and vaccine lot/batch number. Ask for a photocopy of the entry. This is important information to have recorded in case your child does have a severe reaction to the vaccine. The information may also be useful to public health authorities in the unusual event that a bad batch or lot of vaccine is not detected before it is distributed and needs to be recalled.

If your child has a severe reaction to the DPT vaccination or a serious physical or behavioral problem you suspect may be related to the DPT shot, notify your physician at once. Ask your doctor to write down details of any reactions to the DPT shot on your child's medical record. This is essential. Also request that he report a severe reaction in writing to the vaccine manufacturer involved, as well as to your state health department and the U.S. Centers for Disease Control. Ask for photocopies of the doctor's written reports as well as a copy of what he has entered in your child's medical records. If the doctor fails or refuses to provide written notice of a severe reaction to the manufacturer of the vaccine, to the state health department, or to the federal government's Centers for Disease Control in Atlanta, Georgia, you have the right to give that notice. You should report the severe reaction in writing to each of these entities as soon as possible, including the fact that your doctor refused to report the reaction, and ask for a written reply confirming your report.

WHAT IS A SEVERE REACTION TO A DPT VACCINATION?

Many children react to the DPT shot to some degree. In one study, local redness, pain and swelling at the injection site were reported[2] following 37.7%, 40.7% and 50.9% of DPT vaccinations, respectively. A 1979 study reported that over 50% of DPT vaccine recipients had temperatures of at least 100°F.[3] and 72.2% had local reactions including redness, swelling and tenderness. Other reactions which have been reported in scientific literature include diarrhea, rashes, sterile abscesses, cough, and vomiting. Although these are usually not characterized as "severe" reactions in the U.S. and generally are not thought to contraindicate further pertussis vaccine, there are some physicians who believe extreme caution should be exercised if a child suffers a relatively strong form of one of these reactions. In 1980, British physician H.B. Valman reported that "A general or local reaction to a preceding dose suggests that the vaccine should be avoided."

The frequency of more serious reactions, such as convulsion, prolonged unconsolable crying, turning blue or shock-like collapse, is a hotly debated subject, as are the long-term consequences of these more severe reactions to the pertussis vaccine. The American Academy of Pediatrics, each of the three drug manufacturers which commercially distribute the vaccine in the U.S., the Public Health Service, as well as physicians and scientists who have conducted research on the vaccine, disagree on what constitutes a severe reaction to the DPT vaccination.

As has been stated previously in this guide, it is important to know what constitutes a severe reaction, because it is generally agreed that those children who react severely to a DPT shot should not receive the "P" or pertussis portion of the DPT shot again (i.e., only receive the "D" (diptheria) and "T" (tetanus) portion of the shot). Some physicians recommend partial or half doses of pertussis vaccine for those children who have reacted to a previous shot. However, it should be noted that some research indicates that half doses may have no effect on the potential severity of a reaction to the vaccine, and the effectiveness of partial doses to prevent the disease has also been called into question. The possibility of your child receiving half doses of pertussis vaccine should be discussed fully with your physician.

SOURCES OF INFORMATION ON ADVERSE REACTIONS

Following are sources of information you may wish to consult to become knowledgeable about adverse reactions and contraindications to the pertussis portion of the DPT vaccine.

Vaccine Manufacturers

The three private drug manufacturers currently distributing DPT vaccine in the U.S. are Wyeth, Lederle and Connaught. Some states also manufacture and distribute pertussis vaccine. As indicated previously, circulars containing information on what the manufacturers consider to be severe reactions and contra-

indications to the pertussis vaccine are included in packages of the DPT vaccine used by physicians. If you would like to read the circular of the particular brand of vaccine your child will receive, ask your physician to give you a copy to read before your child is vaccinated.

American Academy of Pediatrics

The American Academy of Pediatrics has published its 1982 Report of the Committee on Infectious Diseases, Nineteenth Edition, also referred to as the "RED BOOK." It serves as a guide for pediatricians and contains information on what the American Academy of Pediatrics considers to be severe reactions and contraindications to the pertussis vaccine. If you would like to read the pertussis section of the RED BOOK, ask your physician to let you read it before your child is vaccinated.

Public Health Service

The Public Health Service Immunization Practices Advisory Committee (ACIP) makes recommendations on the use of vaccines. Its most recent recommendations appeared in the August 21, 1981 Morbidity and Mortality Report published by the Centers for Disease Control. These recommendations contain information on what the Public Health Service considers to be severe reactions and contraindications to the pertussis vaccine. If your child is vaccinated at a public health clinic, the physicians at the clinic should have a copy of these ACIP recommendations and you may ask to read them before your child is vaccinated. You may also be able to obtain a copy of these recommendations by writing to the Centers for Disease Control in Atlanta, Georgia.

Scientific Literature

Scientists and physicians throughout the world have been studying pertussis disease and severe reactions to the pertussis vaccine for the past 50 years, and there is a considerable amount of literature on this subject. A good library, particularly a medical library at a community hospital or university, will give you access to these scientific studies. A selective reference list prepared by Dissatisfied Parents Together is attached if you want to research pertussis and the pertussis vaccine further.

IDENTIFYING SEVERE REACTIONS

Many medical experts and reports have recognized that the pertussis part of the DPT vaccine can cause certain severe reactions. These reactions may include:

1. Convulsions
2. Collapse or shock-like episodes
3. Persistent crying
4. High temperature
5. Encephalopathy (brain injury)
6. Excessive somnolence (sleepiness)

(Although these health problems may result from causes other than reaction to pertussis vaccine, they should be immediately reported to your doctor, whatever the cause.)

Because identifying a severe reaction to the DPT vaccine is the combined responsibility of the parents and the physician, you should watch your child very carefully and monitor his temperature for at least 72 hours after he receives the DPT shot. At night, check him frequently. You should immediately report any of the following reactions to your physician:

Convulsions

Webster's Third International Dictionary (1976) defines a convulsion as a "spasmodic contraction of the muscles."[1] There are different kinds of convulsions and they may occur with or without a fever.

clonic: A "convulsion marked by alternating contracting and relaxing of the muscles."[4]

tonic: A "prolonged contraction of the muscles."[4]

local (or focal): "Any minor spasm affecting but one muscle or one part or members (of the body)."[4]

febrile: "Those (convulsions) associated with high fever, occurring in infants and children."[4]

petit mal: "Attacks of brief impairment of consciousness often associated with flickering of the eyelids and mild twitching of the mouth."[5] "A brief loss of consciousness, lasting a few seconds. A few 3-per-second blinks or jerks of eyelids and sometimes arms may be conjoined."[6]

generalized convulsion (grand mal): "It begins with a sudden loss of consciousness, a cry, a fall to the ground, tonic then clonic movements of the muscles of the cranium and limbs, sometimes sphincteric incontinence, and other autonomic disorders. The motor activity soon terminates, leaving the patient in a state of coma, which lasts for many minutes or even as long as a half-hour. As the coma recedes, mental confusion, drowsiness and headache become evident."[6]

In their 1978 study of adverse reactions to DPT shots, Cody, Baraff, et al. reported that convulsions occurred in 1 in 1750 vaccinations. (This study is referred to as "Cody, Baraff et al. in the following paragraphs of this section.)[2]

Collapse or Shock-like Episodes

The terms "collapse," "shock-like episode," and "hypotonic or hyporesponsive episode" are used to describe one type of serious reaction to pertussis vaccine. Cody, Baraff et al. state, "All such reactions observed occurred within ten hours of immunization and usually within four hours. Characteristically, the infant or child was pale, hypotonic, and unresponsive to his parents for a period ranging from ten minutes to 36 hours."

George W.A. Dick in a British study "Reactions to the Pertussis Component of Quadruple and Triple Vaccines" published in 1967, described shock and collapse following DPT vaccination:

"About three hours after inoculation, the baby suddenly becomes marble white, cold and collapsed and remains like this for about 15 to 30 minutes; after recovery, it often remains pale and listless for a few hours. Some mothers have said that their babies became unconscious at the onset of the collapse, others thought their baby was dead. When babies developing this syndrome were followed up a year later, they seemed healthy and appeared to have passed the usual milestones normally. It is, however, difficult to exclude the possibility of permanent damage. On observing these reactions, parents quite naturally urgently summoned a doctor, but by the time he arrived the baby had usually recovered from the severe episode and some mothers were quite unable to convince their physicians that anything really serious had happened. Because of the unavoidable delay in getting to their patients, very few doctors have seen the early stage of this syndrome (except in their own infants). It is quite possible that it is more frequent than is generally believed, for it could well pass unobserved even by the mother."

Cody, Baraff et al. also state, "Collapse or shock-like state following pertussis immunization has been reported on numerous occasions. The majority of these hypotonic hyporesponsive episodes seem to be self-limited with no residue. However, there have been reports of death from apparent shock following pertussis immunization."[2]

Persistent Crying

"Uninterrputed, continuous crying distinctly unusual for the infant or child. In most cases, the parent likened the character of the cry to that of a pain cry. The cry usually began three to six hours following immunization and lasted from one to 21 hours."[2] Cody, Baraff et al. reported that 3.1% of vaccine recipients experienced persistent crying.

High Pitched Screaming

"An unusual cry was defined as a cry of unusual character, usually described by the parents as a high pitched scream. It was a cry that the parents claimed they had never heard their child produce before."[2]

"Unusual high pitched crying has been previously reported after DTP immunization. Several authors feel that this should be classified as a major reaction; however, the significance of this reaction is unknown. The subjectivity in reported high pitched crying makes it difficult to develop reliable estimates of its frequency. We found 17 infants who appeared to have had a truly unusual high pitched cry within 48 hours of immunization, and incidence of 1.1:1,000 DTP immunizations."[2]

George W.A. Dick in his previously mentioned 1967 British study stated, "The reaction of persistent and uncontrollable screaming comes on about two hours after inoculation. It starts with a bout of screaming and the baby cannot be comforted or quieted. This screaming often lasts for about an hour and usually terminates with a period of exhaustion lasting for about 30 minutes, during which time the baby is restless but quiet. Screaming bouts then commence again and eventually the baby falls into a deep sleep for as long as twelve hours."

Dr. Edward A. Mortimer, Jr. in an article, "Pertussis Immunization: Problems, Perspectives, Prospects," published in 1980 stated, "Neurologic reactions, particularly in infants, are always worrisome, but two of the four that may be classified as such are really of unknown origin and are only presumed to be neurologic. One is an episode of prolonged, uncontrollable crying that begins within a few hours of the injection and lasts for at least an hour (sometimes for as long as six hours or more); this persistent screaming syndrome has been referred to by some investigators as "high-pitched crying" which is reminiscent of the "encephalitic cry" sometimes associated with brain damage, but others have reported that the crying associated with pertussis vaccination is simply protracted."

Cody, Baraff et al. reported 0.1% of the DPT recipients in their study had high pitched screaming.[2]

High Temperature

Each of the three drug manufacturers, Wyeth, Lederle and Connaught, states that a temperature more than 103° F. (39° C.) is a severe reaction and a contraindication to further pertussis vaccine. The American Academy of Pediatrics RED BOOK and the Public Health Service ACIP Recommendations state that a temperature more than 104.9° F. (40.5° C.) is a severe reaction and a contraindication to further pertussis vaccine. A fever greater than 103° F. (39° C.) was reported to have occurred in 6.1% of DTP recipients in the Cody, Baraff et al. study. You should ask your physician to give you instructions on how to take immediate steps to lower your infant's high fever if it should occur following a DPT vaccination. A high temperature is of particular concern because, in infants and children, it can trigger febrile convulsions.

Encephalopathy (Brain Injury)

The Public Health Service ACIP Recommendations define this as "Encephalopathy, with or without convulsions, manifested by bulging fontanel, changes in the level of consciousness, or focal neurologic signs· the encephalopathy may lead to permanent neurologic deficit."

Dr. Vincent Fulginiti in an article published in 1980 titled, Bacterial Immunizations," stated, "The estimates of frank encephalopathy after pertussis vaccination have ranged from as many as 1/6,000 doses to as few as 1/1,000,000 doses. Many experts are of the opinion that an incidence of 1/50,000 to 100,000 is the most likely rate in the United States. As of this writing, the precise incidence is unknown. The outcome of encephalopathy syndromes may range from almost an immediate recovery to death. One British study concludes that the risk of residual brain damage from pertussis immunization is 1/300,000 immunizations. Once again, difficulty in ascribing a particular encephalitic reaction to pertussis immunization is highlighted by non-pertussis encephalitic syndromes occurring in the age group receiving vaccine."

Cody, Baraff et al. stated in their study, "Stewart has stated that brain damage could have a frequency of 1:6,500 vaccinated children (a rate of 1:32,000 immunizations). Hannik reported a rate of 1:500,000 in Holland and Strom in 1967 published a rate of 1:170,000 in Sweden. . . At this time there are no estimates available for products licensed in the United States."[2]

Excessive Somnolence

"Drowsiness; sleepiness; a condition of semi-consciousness approaching coma."[5] An article by E.R. Gonzales in the July 1, 1982 Journal of the American Medical Association, states, "Leonard P. Rome, M.D., chairman of the AAP's Chapter Chairmen's Committee, points out that "excessive somnolence," for instance, refers to a state of sleep from which the infant cannot be aroused; a drowsy child who wakes up to eat is not experiencing this reaction."

POST VACCINATION MONITORING

It cannot be overemphasized that parents should monitor their children carefully for at least 72 hours after each DPT shot is given. The first 24 hours post-vaccination is an especially important time to be alert. Although identifying a severe reaction to the pertussis vaccine is the combined responsibility of parents and doctors, only parents can be with the child 24 hours a day. If you have any reason to be concerned that your child may be having a severe reaction, notify your doctor at once.

CONCLUSION

It is important for us, as parents, to be equally concerned and knowledgeable about the risks of pertussis disease as we are about the risks of the current pertussis vaccine. Pertussis disease has the potential to cause seizures, brain damage, and even death, just as the pertussis vaccine can. Most of America's medical community believes that the "risk of serious illness or death from the highly infectious pertussis disease is far greater than the possible effects which can be caused by the vaccine."

However, recognition of and concern about the dangers of pertussis disease do not diminish our need and responsibility to recognize and be concerned about the dangers of the pertussis vaccine. The challenge today is for parents, physicians, scientists, manufacturers and health officials to recognize the risks of both the disease and the vaccine and work together to assure production of a safer, effective pertussis vaccine for America's children.

A Final Note About Dissatisfied Parents Together

In order to continue our research and information campaign to protect the health of our children, we need your help and support. Please write or call us and join our organization. Contribute financially to our start-up efforts - $5, $10, $15 or more if you can. Postage, printing and telephone calls are expensive. All contributions are tax deductible. We also need your active personal support as well as your dollars and welcome anyone who wants to hlep us in our day-to-day activities. Please write (including your return address and telephone number) to:

Dissatisfied Parents Together
Box 563
1377 K St. NW
Washington, D.C. 20005

We have an answering service. If you call (202) 543-4211 and leave your name and telephone number, we will return your call as soon as we can.

References

[1]Weissman. "Pertussis Vaccine: What's Right for Our Children?" Vital Signs. George Washington University Health Plan (July-August 1982). p. 1.

[2]Cody, C., Baraff, L., Cherry, J. et al. Nature and Rates of Adverse Reactions Associated with DTP and DT Immunizations in Infants and Children. Pediatrics. 1981;650-659.

[3]Barkin, R. and Pichichero, M. Diptheria-Pertussis-Tetanus Vaccine: Reactogenecity of Commercial Products. Pediatrics. 1979; 63:2:256-260.

[4]Dorland's Illustrated Medical Dictionary, 26th Edition (1981).

[5]Stedman's Medical Dictionary, 23rd Edition (1976).

[6]Harrison's Principles of Internal Medicine, Ninth Edition, (1980).

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The Johns Hopkins Hospital

Department of Neurology

April 12, 1983

Ms. Bonnie Kessler
Epilepsy Foundation of America
4351 Garden City Drive
Landover, Maryland 20785

Dear Bonnie:

I read with great interest the document prepared on pertussis by the Dissatisfied Parents Together group. I think it is exceedingly well done, and relatively unbiased. I was struck in reading the first several pages that they suggest the parents ask questions of the physicians which I think few physicians are able to answer. They are, quite fair questions. I wonder if perhaps the Academy of Pediatrics should consider developing specific responses to these questions for the pediatricians and family practitioners.

I did have a bit of a problem with their section on "What Is A Severe Reaction." I think that they might want to consider reorganizing it to talk about the severe reactions first, and then come back to the discussions on pages 6 and the top of 7. They also might want to point out a little bit more clearly what, if any, are the discrepancies between the Public Health Service, the Academy, and the manufacturers in their discussion of severe reactions.

Their paper attempts to serve two purposes at once. One, is to alert parents as to what potential reactions might occur, and the questions they might ask their physician in deciding whether or not to have the shunt. A second purpose appears to be the reporting of data to the organization. I think they might better serve their membership by separating these two things a little more clearly for they have two very different purposes. By and large, I think they have done an excellent job and I hope that they are sharing this with the Academy of Pediatrics and the Red Book Committee.

Sincerely,

John M. Freeman, M.D.

JMF/meb

600 North Wolfe Street, Baltimore, Maryland 21205 (301) 955-3282

TESTIMONY BEFORE THE ENVIRONMENTAL MATTERS COMMITTEE, MARYLAND HOUSE OF DELEGATES, 3/16/83, BY JEFFREY H. SCHWARTZ, ON BEHALF OF DISSATISFIED PARENTS TOGETHER (DPT)

I. Introduction

Good afternoon. My name is Jeffrey H. Schwartz. I live in Maryland and I am here to testify on behalf of Dissatisfied Parents Together (DPT).

I want to thank the House Environmental Matters Committee for its consideration of H.B. 1279, a bill concerning pertussis and the pertussis vaccine, and for allowing our organization the opportunity to appear and present this testimony today.

To summarize, I would like to cover a number of points including the following:

* How my family became concerned about the issues under consideration here today, who and what Dissatisfied Parents Together (DPT) is, and what interest we have in the bill that is now before the Committee;

* What the problem is that we believe needs to be addressed (specifically what is the problem with pertussis vaccines, with the way they are being administered in Maryland, and with the law and regulations which mandate the vaccine's use today in Maryland);

* What we understand H.B. 1279, as proposed to be amended, would do to help solve these problems;

* Why we believe legislation is necessary to address these problems;

* What the reaction of our group is with respect to the legislation and amendments; and

* Some brief closing thoughts.

II. Dissatisfied Parents Together (DPT)

Turning to the first of these points, let me explain a bit about who I am and who and what Dissatisfied Parents Together (DPT) is. As indicated previously, my wife and I are Maryland residents. We are also the parents of a two year old daughter -- Julie -- who we believe has been severely injured by the pertussis part of the "DPT" or "DTP" vaccine. (This is a vaccine required by State law and regulations to be given to all children in Maryland before they are permitted to enter school. It contains three vaccines in one - the diptheria (D), tetanus (T) and pertussis (P) components.) Our concern here today is only with the "P" part of the vaccine (i.e., the pertussis part of "whooping cough" vaccine as it is commonly known).

In the testimony which follows, I will talk about Julie briefly. This is not because her situation is unique; unfortunately, it is an all too common reflection of the catastrophic problems which parents and their children throughout Maryland and the nation are experiencing.

Julie was fine when she was born and remained healthy until four months later -- the day of her third DPT shot. She get her shot in the morning of July 3, 1981. By noon she seemed to be "startling" frequently, without apparent reason. Late in the afternoon she went into a grand mal seizure that lasted approximately 35 minutes. She was rushed to the emergency room and admitted with what the doctors noted was a reaction to her DPT shot. That day - July 3, 1981 - was a day which in our family will "live in infamy."

Since that time we have had an almost indescribable chain of events and feelings. In the almost two years since then, Julie has had approximately 50 grand mal seizures and many more petit mal (or mini-) seizures. One of the grand mal seizures lasted 45 minutes to an hour. Another occurred at night and lasted we don't know how long -- since we found her in bed in the morning still seizing. She continues to have seizures today -- in fact, more frequently than ever -- even though she is now taking three anti-convulsant drugs.

As a direct result of the longest seizure, she developed a right-side hemi-paresis at 11 months (this basically like a stroke, in which she lost all right side function). In one day, she went from a baby who was able to stand and cruise around the furniture and to say a few words to an invalid. She could not stand. She could not sit up. She could not even smile. She lost all speech.

She has been diagnosed as having vaccine-induced epilepsy and brain damage. She has also been diagnosed as being "learning disabled" as a result of her neurological problems. She requires special one-on-one speech therapy, fine and gross motor therapy. She gets some form of therapy five days a week now. She still is basically unable to walk. She cannot say two syllable words -- other than "mama" or "dada." The repeated seizures further delay her developmental progrss every time they occur.

As a result of all these problems -- including medications she is taking -- she is frequently very irritable, crying and whiny; she also exhibits evidence of hyperactivity and low attention span -- classic symptoms of neurologically impaired children.

Most recently she has been diagnosed as suffering from swelling of one side of her brain -- a potentially life-threatening condition if not corrected. As a result, she is now taking a fourth drug.

Julie has been hospitalized at least four times. Each of these hospitalizations was preceded by a telephone call to the rescue squad (because Julie was in the middle of a seizure that would not stop), a tearful and frightening (for us) ride in an ambulance, and the unspeakable anxiety of waiting in an emergency room as medical personnel

worked frantically on our child. Julie has had a number of tests including repeated CT scans, electroencephalographs (EEG's), and a radioisotope brain scan, a spinal tap, numerous blood tests, a genetic screen, repeated developmental tests and doctors' examinations. All this before the age of two. And the prognosis for her future is uncertain at best.

I can't find any way to express adequately the emotional costs Donna and I have had to endure without respite over the past two years -- the fear, the pain, the sorrow, the confusion, the anxiety, the helplessness, the rage, the hopelessness, the unrelieved exhaustion and the depression. These are the right labels for the feelings, but they cannot convey what the experience has been like. It has felt like a nightmare -- with no waking, no escape. (This is not to mention the financial costs and the social costs that we have had to pay.) Nor does this tally up what is perhaps most important -- the pain and loss that Julie has suffered, continues to suffer, and may well suffer for the rest of her life. Other families have suffered far worse even than we.

Dissatisfied Parents Together (DPT) began to form in April 1982, when we and a group of other parents in Maryland, Virginia and D.C. came to realize that Julie's problems are not unique. As a result of a local television documentary, we learned that the pertussis vaccine had been reported in the medical literature for 50 years to be capable of causing serious reactions. These reactions may include death, brain damage, seizures and epilepsy, paralysis, blindness, and related neurological impairments and developmental disabilities.[1]

Dissatisfied Parents Together (DPT) was thus incorporated in June 1982 as a non-profit, tax exempt foundation. The primary purpose of Dissatisfied Parents Together is to promote greater public awareness of the dangers both of pertussis and of current pertussis vaccines. The group seeks to help bring about a safer, more effective vaccine for the future and to assist those who have been seriously injured by the disease or the vaccine in the past.

This statement of purpose emphasizes several key points about our group and our goals:

1. We are not anti-vaccination generally or opposed to child immunization programs. We support properly structured disease prevention programs.

2. We are not focusing on vaccines other than the pertussis part of the DPT vaccine.

3. We are not indifferent to the dangers of pertussis disease. We acknowledge and are concerned about its dangers as much as we are about the dangers of the vaccine. The most serious results of the disease and of a reaction to the vaccine can be similar.

4. We are not advising parents to withhold the pertussis vaccine from their children. We neither oppose, nor recommend, pertussis vaccination at this time.

What Dissatisfied Parents Together seeks to do is to promote discussion of whether the benefits of the current pertussis vaccine really do outweigh its risks; to assure a more informed parent population, so that we can better protect the health of our children; and to create a more effective system for gathering the information necessary to decide whether and in what circumstances pertussis vaccination should be mandated or waived. (A copy of the official goals of the organization is appended to this testimony.)

Since its organization, Dissatisfied Parents Together has concentrated its efforts on reading the medical literature on pertussis and the pertussis vaccine; discussing the information with doctors, health officials and parents; and preparing a parent information booklet on pertussis vaccine. In short, we are committed to taking a deliberate and responsible approach to this difficult problem, to learning the facts, and to working with the system to better protect the health of our children.

At present, DPT has had approximately 3000 parents, grandparents and individuals from all of the 50 states contact us for information. Many have reported serious reactions to the pertussis vaccine, and others have made offers to contribute money, time and effort to carry out the foundation's goals.

III. The Problem

As we see it, the problem that needs addressing has ten major elements. First, the pertussis vaccine that is in use today is much different from more modern vaccines. It is probably the oldest, crudest, least well-understood, and most dangerous vaccine that is licensed. This is admitted even by the strongest proponents of the vaccine -- including Drs. Mortimer[2] and Fulginnitti[3] of the American Academy of Pediatrics and Dr. Manclark[4] of the Food & Drug Administration:

> Pertussis vaccine is an entirely different story. This vaccine is crude and impure by the standards of many other immunizing agents. It comprises whole killed organisms, which contain many proteins of varying nature and possible toxicity. There is no question that pertussis vaccine is more reactive than we would like, and that some of these reactions are associated with permanent sequelae, such as disabling cerebral damage. Other reactions to pertussis vaccine, such as a peculiar high-pitched screaming that persists and occurs in some infants who receive the vaccine or excessive and worrisome sleepiness that occurs after the vaccine, are of unknown importance in terms of whether they induce permanent sequelae. Unfortunately, although these

> reactions attributable to pertussis vaccine have been known for some years, the precise rates at which they occur have not been defined. Estimates of the benefit-risk ratio of pertussis vaccine, in the light of these low but undesirable rates of reactivity, are further complicated by the fact that the protective efficacy of pertussis vaccine is open to challenge.[2]

Second, what makes this a "legislative" problem, not merely a "medical" problem is that this vaccine is legally mandated by the laws and regulations of the State of Maryland. Each Maryland school child must receive the pertussis vaccine before he or she may enter school.

Third, the law and regulations in Maryland give parents no discretion as to whether their children should receive the vaccine. "Informed consent" is not required. Unlike 19 other states which permit parents to object on grounds of philosophical or personal conviction, Maryland law and regulations allow no option for parents to have their children excused from receiving this admittedly "crude" vaccine.

Fourth, in Maryland neither the laws nor the regulations permit licensed doctors much discretion as to whether or not their patients should receive the vaccine. This is particularly a problem for children who, because of other health problems, are at high risk of severely reacting to the vaccine.

Fifth, parents all too frequently receive little or no information as to the possible side effects and real risks of the vaccine, particularly children served by private physicians. A repeated message from the thousands of letters we have received to date is, "Our doctors never told us the vaccine could cause these problems," and "Where can we get the information we need to make informed decisions to protect our children's health?"

Sixth, physicians all too frequently do not acknowledge, let alone report to proper authorities, serious adverse reactions to the pertussis vaccine (or even the possibility that the vaccine may have caused such a reaction). Currently there is no legal duty for the doctor to report serious reactions, and parents are not aware that they may have the right to make such reports. In addition, many doctors are not routinely keeping records of the vaccine and lot number they administer. Many also fail to record parents' reports of serious reactions. Thus, many parents have written saying, "Our doctor refuses even to admit the possibility that the seizures could come from the DPT shot, even though our child never had them before and they started the day of the shot." This underreporting of severe reactions is also well documented in the medical literature, even by the vaccine's advocates.[2]

Seventh, the contraindications policy of the state health department appears to be so strict that pertussis vaccination is compelled, even for children at high risk of serious reaction to the vaccine. This includes children who have epilepsy, febrile seizures, serious neurological handicaps, severe allergies, other inconsistent medications, excessive fever susceptibility, and siblings of those who have had serious reactions to pertussis

vaccine. Maryland's practice in some or all of these regards runs counter to the recommendations of the vaccine manufacturers and to health agencies in many countries in Europe. The criteria may even vary from county to county within Maryland.

Eighth, even those "contraindications" which are set forth in Health Department guidelines are too often violated by doctors. Parents, being uninformed of these "contraindications", may not be able adequately to inform the doctors of these conditions or raise appropriate questions. Many of the letters we've received show these contraindications being ignored -- with the child receiving more shots after serious reactions to earlier ones. The British National Childhood Encephalopathy Study showed that in about 25-40% of the permanent injury cases studied, there were clear contraindications to administration of the vaccine.[5]

Ninth, assertions by advocates of the vaccine that the benefits of the vaccine outweigh the risks cannot be documented in practice, because of these failures to diagnose serious reactions and because of underreporting of the serious reactions which are diagnosed. Moreover, there is no proof in the medical literature that we have been able to find so far that supports the assertion that benefits outweigh the risks for children in high risk categories.

Finally, the overall benefits-risks judgment provides no comfort whatsoever to the families whose children are severely damaged by the vaccine. Moreover, despite the fact that the State mandates administration of the vaccine, the State neither takes the responsibility (nor mandates the manufacturers to do so) for the tremendous medical, rehabilitation, special education, emotional, and custodial care costs which may be incurred by families of vaccine-damaged children.

As indicated previously, many of the letters we've received tell of far worse tragedies than have befallen our family. Normal, healthy children have died the same or next day after receiving the shot. Others have 50-100 seizures a day, have intellectual capabilities of less than a year or two, and will require permanent custodial care (or even institutionalization) for perhaps 40-50 more years. Yet despite these potentially enormous costs, the child and parents alone often bear the entire costs of what must be considered an involuntary draft. Although the vaccination program is supposedly undertaken for the benefit of the entire society, the society to date feels no responsibility to care for those wounded or killed in this war against infectious disease. We find that reality unconscionable. We would never treat our soldiers so callously. Why do we treat our children so?

These ten elements thus make up our view of the problem that needs to be addressed.

IV. The Need for Legislation

In our view, strict compulsory vaccination legislation helped cause some of the above problems, and new legislative authority and guidance is needed if some of these problems are to be addressed. Currently the state health department appears to lack some of the authority necessary to respond to these concerns. In other respects, the department appears unwilling or unable to respond adequately, from our point of view. Voluntary physician education programs simply are not an adquate answer.

The problem of the pertussis vaccine's potential danger has been known for 50 years. Many parents are starting to believe neither the health care system, nor the government can be trusted. Preventive medicine programs are coming into disrepute with many. Unless the legislature takes the steps necessary to restore eroding public confidence now, the anger and mistrust may well grow to dangerous levels.

V. Reaction to H.B. 1279, with Proposed Amendments

Dissatisfied Parents Together (DPT) strongly supports enactment of H.B. 1279, with the proposed amendments which we understand are being offered by the sponsors of the bill. This does not mean that we think the bill is perfect in every respect, that it responds to all the concerns we have raised, or that it reflects the entire program of Dissatisfied Parents Together (DPT). Plainly, it does not.

For example, the model state law on pertussis and the pretussis vaccine which we are preparing contains several provisions which are not included in H.B. 1279, or its amendments. These additional provisions include:

1. A system for no-fault compensation of individuals severely damaged by pertussis vaccine, based on a fee or tax on the vaccine.

2. A finding that a safer pertussis vaccine needs to be developed and made commercially available, and a mandate to the state health department to cooperate with the federal FDA and other appropriate entities in helping to develop and test such a vaccine; and

3. A provision permitting an individual parents to exercise a right to philosophical objection against pertussis vaccination of their children, at least until the FDA licenses a pertussis vaccine which it finds to be substantially safer than currently available vaccines (or at the very least, a requirement for a health department study of the "philosophical objection" provisions in the 19 states which allow them to determine whether pertussis rates are higher than in those states which do not permit such provisions).

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Nevertheless, Dissatisfied Parents Together believes that the bill H.B. 1279, with the proposed amendments, is a welcome and long-overdue attempt to begin to respond to the concerns voiced above. In effect, the bill is reasonably simple and straightforward. It accomplishes four main goals:

(1) Parent information: It assures that parents will be given the necessary information to help recognize, monitor for, prevent, and/or respond quickly to any serious reactions to the vaccine;

(2) Recordkeeping and Reporting: It assures that doctors will keep the necessary records and that doctors and/or parents will make the necessary reports on pertussis and severe reactions to the pertussis vaccine;

(3) Surveillance: It assures that the state health department will maintain an adequate field surveillance system to verify reports of pertussis and severe vaccine reactions; and

(4) Flexibility: It provides for the state health department and licensed physicians to establish a more flexible system, so that high risk children may be excused from mandatory pertussis vaccination, (but only if the doctor finds that the risks from the vaccination would exceed the benefits to the child and to society.)

While this is not as much flexibility as we would prefer to see in the system, we think H.B. 1279, with proposed amendments, represents a reasonable attempt to balance the needs of the individual with the needs of the community to protect itself against infectious disease. We support its enactment and urge members of this Committee to do likewise.

VI. A Brief Closing Note

Dissatisfied Parents Together (DPT) would like to thank the sponsors of H.B. 1279 for raising this important set of issues for the consideration of the Legislature and citizens of the State of Maryland. Again, we would like to thank the Committee for its hearing on this bill and amendments. We believe Maryland could play the role of vanguard of all the states in restoring public confidence in the Nation's immunization program, while more sensitively protecting the health and rights of individual parents and children.

We think a special debt of gratitude is owed to those whose pioneering efforts (and dearly paid prices) have made possible the level of public awareness of these issues which we are seeing today. In particular, we wish to recognize and honor Mr. and Mrs. James Grant and their son, Scott; Mr. and Mrs. Dan Resciniti and their sons, Tony and Leo; Mr. & Mrs. Lorenzo Browne and their son, Reynaldo; Mr. & Mrs. Conley Yankovitch and their daughter, Abra; Evelyn Gaugert and her daughter, Polly; Mr. and Mrs. Holcomb and their daughter, Kelli; Dr. Madsen and his medical colleagues

who, since 1933 have studied and warned of the danters of pertussis and the pertussis vaccine; and the journalists, public interest researchers, medical personnel, government officials, and attorneys who have helped bring this information to light.

I would be pleased to answer any questions or provide any information the Committee may request.

Doull, et. al., "Active immunization Against Whooping Cough," American Journal of Public Health (Nov. 1936), pp. 1097-1105.

Notes

1/ See Madsen, "Vaccination Against Whooping Cough," JAMA, (July 15, 1933), pp. 187-8; Byers and Moll, "Encephalopathies Following Prophylactic Pertussis Vaccine," Pediatrics (April 1948), pp. 437-457; Toomey, "Reactions to Pertussis Vaccine," JAMA (February 12, 1949), pp. 448-50; Globus and Kohn, "Encephalopathy Following Pertussis Vaccine Prophylaxis," JAMA (Oct. 22, 1949), pp. 507-509.

2/ Mortimer, "Problems with Immunization Against Infectious Disease," Pediatric Research (May 1979), pp. 684-5. See also Mortimer, "Pertussis Immunization: Problems, Perspectives, Prospects," ~~Medic.~~ Hospital Practice (October 1980), pp. 103-118.

3/ Harrison + Fulginiti, "Bacterial Immunizations," American Journal of Diseases of Childhood (Feb. 1980), pp. 184-6.

4/ Manclark, "Pertussis Vaccine Research," Bulletin of WHO, (1981), pp. 9-15.

5/ Joint Committee on Vaccination and Immunization, Whooping Cough Vaccination (1981).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Centers for Disease Control
Atlanta, Georgia 30333

July 20, 1983

Mr. Jeffrey Schwartz
Dissatisfied Parents Together
Box 563, 1377 K Street, NW
Washington, D.C. 20005

Dear Mr. Schwartz:

Enclosed are answers from CDC and FDA to questions 1-7, 10 and 11 and partial answers to question 9 contained in your letter of April 29. Because answers to questions 8, the remainder of 9, and 12 will require legal review, they will be submitted at a later date.

In its response to questions relating to pertussis vaccines and manufacturers, FDA has included information on the three licensed companies (Connaught, Lederle, & Wyeth) which are currently engaged in interstate commerce. Information on the Michigan and Massachusetts products is not included because, although they are also licensed, they are not distributing their DTP products for sale interstate.

Sincerely yours,

Walter R. Dowdle, Ph.D.
Director, Center for Infectious Diseases
and
Chairman, Interagency Group to Monitor
Vaccine Development, Production and Usage

Enclosures

1. PLEASE PROVIDE THE FOLLOWING INFORMATION WITH RESPECT TO EACH REPORT OF A POSSIBLE REACTION TO, SIDE EFFECT OF, OR COMPLICATION ARISING AFTER, THE ADMINISTRATION OF ANY VACCINE CONTAINING PERTUSSIS WHOLE CELL OR EXTRACTED MATERIALS, OF WHICH HHS DEPARTMENT (FDA, CDC, OR NIH) IS AWARE. . .

The monitoring system for illnesses following immunization operated by the Centers for Disease Control and the form on which illness is reported are described in Attachments 1-4. All forms received for the years 1979-81 have had identifying information removed and have been microfilmed. They are available at a cost of $25.20 from the Centers for Disease Control, Atlanta, Georgia 30333. These microfilms include most of the information requested in Question 1 with the exception of: State and locality in which vaccine was administered, nature of the licensure of the person administering the vaccine, number of pertussis inoculations received prior to this inoculation, and followup beyond 1 week. All reports at CDC 1979-1982 have been received on these forms which have been submitted through State health departments. 1982 forms are in process of being readied for microfilming; it is anticipated that they will be available before the end of this fiscal year. To our knowledge, reactions to DTP reported to CDC before 1978, are in the Federal Record Center and may be in labeled files although individual reports, letters, or memoranda may have been filed with other materials. To the best of our knowledge all reports made to State or local health departments of significant adverse reactions following DTP vaccination would have been reported to CDC or to the Office of Biologics, FDA. Information concerning adverse reactions to pertussis containing vaccines reported to FDA for the years 1977 through 1983 from a variety of sources are in Attachment 5.

2. WITH RESPECT TO "REPOOLING" OR "REWORKING" OF VACCINES CONTAINING PERTUSSIS WHOLE CELL OR EXTRACTED MATERIALS, PLEASE PROVIDE THE FOLLOWING INFORMATION:

   (a) A COPY OF RELEVANT FDA REGULATIONS, GUIDELINES, PROCEDURES, ADVISORIES, ETC, GOVERNING THE "REPOOLING" OR "REWORKING" OF SUCH VACCINES;

   (b) A BRIEF STATEMENT OF THE CONDITIONS UNDER WHICH "REPOOLING" OR "REWORKING" OF THE VACCINE IS PERMITTED UNDER CURRENT FDA REGULATIONS, GUIDELINES, ETC. AND OF THE LIMITATIONS ON "REPOOLING" OR "REWORKING" WHICH ARE IN EFFECT UNDER THOSE REGULATIONS, GUIDELINES, ETC,;

   (c) THE NUMBER OF TIMES A PERTUSSIS-CONTAINING LOT OR BATCH MAY BE "REPOOLED" OR "REWORKED" IN WHOLE OR PART;

There are no published regulations or guidelines which deal specifically with the "repooling" or "reworking" of pertussis vaccines. However each manufacturer has a specific internal procedure which he follows. Vaccines which have been "repooled" or "reworked" are assigned a new lot number. That

lot is then subjected to all tests and procedures required for the release of a new vaccine lot. Those tests results are recorded in the product protocol and in the records retained by the manufacturer.

(d) THE MANUFACTURER'S NAME, BATCH AND LOT NUMBER FOR EACH PERTUSSIS-CONTAINING VACCINE WHICH HAS BEEN "REPOOLED" OR "REWORKED" AT LEAST ONCE, SINCE 1/1/50;

Information identifying vaccine lots that have been "repooled" or "reworked" is not held by the Office of Biologics, but is a part of the manufacturing record retained by the manufacturer.

(e) WHETHER "REWORKING" OR "REPOOLING" CAN UNDER SOME CIRCUMSTANCES RESULT IN THE VACCINE'S REACTOGENICITY OR NEUROTOXICITY INCREASING (AND, IF SO, THE CIRCUMSTANCES UNDER WHICH THIS MAY OCCUR).

There are no data of which we are aware to support the possibility that "repooling" or "reworking" can increase a vaccine's reactogenicity.

(f) THE MANUFACTURER'S NAME, BATCH AND LOT NUMBER FOR EACH PERTUSSIS-CONTAINING VACCINE WHICH FAILED EITHER THE POTENCY OR TOXICITY TESTS (OR BOTH) WHEN TESTED EITHER BY THE MANUFACTURER OR BY THE FDA (SINCE 1/1/50 - PRESENT).

All vaccine lots which are submitted to the Office of Biologics (OB) with a release protocol have passed all of the manufacturer's tests including those for potency and toxicity. Occasionally a manufacturer may submit a sample for concurrent testing at OB and at the manufacturing facility. Such lots are not considered for release until a protocol with all of the required information is submitted by the manufacturer. In some instances, concurrently tested lots are withdrawn by the manufacturer and not submitted with a release protocol. Data most readily available at OB are presented in Attachment 6, and include the manufacturer's name and lot number for each vaccine containing a pertussis vaccine component submitted with a release protocol that has failed the OB's tests for pertussis potency and/or toxicity since 1978. To provide data prior to 1978 would require a laborious search of records some of which are in storage in the Federal Records Center.

3. (a) PLEASE SUBMIT ONE COPY EACH OF ALL DOCUMENTS WHICH FORMED THE BASIS FOR INITIAL FDA LICENSURE DECISIONS WITH RESPECT TO EACH CURRENTLY LICENSED PERTUSSIS-CONTAINING VACCINE SOLD IN THE UNITED STATES. (IF THIS IS NOT POSSIBLE, PLEASE EXPLAIN WHY AND PROVIDE FULL CITATIONS TO THE RELEVANT DOCUMENTS.)

Copies of all documents which formed the oasis for initial licensure decisions with respect to each licensed pertussis-containing vaccine currently sold in the United States are found in Attachment 7. It should be noted at the time of licensure of these DTP vaccines, some manufacturers obtained a license for each individual component of a combined vaccine, prior to filing a license

application for the combined product. Therefore, we have enclosed a copy of the appropriate component's approval documentation to supplement the manufacturer's initial license approval for DTP.

(b) PLEASE SUBMIT ALL ADVERSE REACTION DATA SUBMITTED BY THE VACCINE MANUFACTURER (WHICH WAS REQUESTED TO PROVIDE SUCH DATA BY THE FDA) IN RESPONSE TO THE FINAL REPORT OF THE PANEL ON REVIEW OF BACTERIAL VACCINES AND TOXOIDS (AUG. 1979).

Attachment 8 responds to this request.

4. (a) PLEASE PROVIDE ALL INFORMATION WHICH TENDS TO SHOW WHETHER THE ELI LILLY COMPANY'S TRISOLGEN PRODUCT WAS MORE REACTOGENIC/NEUROTOXIC, LESS REACTOGENIC/NEUROTOXIC, OR ABOUT THE SAME AS WHOLE CELL PERTUSSIS-CONTAINING VACCINES.

Trisolgen is the trade name of a DTP adsorbed vaccine manufactured by Eli Lilly. The pertussis component of this product is an extracted, rather than a whole-cell, antigen. This vaccine was distributed from the early 1960's until the mid 1970's, at which time Eli Lilly ceased the manufacture of most biologics. There are few published studies of which we are aware in which this vaccine was compared to whole cell vaccines. In the report of Weihl et al., (Am. J. Dis. of Children 106: 124, 1963) there are data which indicate that children who received the extracted vaccine (Trisolgen) had fewer febrile reactions (defined by these investigators, as febrile responses greater than 0.5 degrees above normal) and fewer local reactions at the site of injection than did children given any of four different whole-cell vaccines. Serious neurological reactions were not described.

This product was reviewed by the Panel on Review of Bacterial Vaccines and Toxoids (see Final Report, Volume 1. August 1979, pp. 293-297). In their report, they state "in the matter of safety, the data give the general impression that the vaccine containing extracted pertussis antigen is somewhat less reactive than whole-cell pertussis vaccine in terms of local and minor systemic reactions. There is not sufficient basis to assume that this vaccine is any more or less safe than whole-cell vaccines in terms of the very low risk of serious encephalopathic reactions which accompanies the use of pertussis vaccines."

(b) PLEASE PROVIDE ALL INFORMATION ON THE REACTOGENICITY/NEUROTOXICITY OF THE WYETH LABORATORIES' EXPERIMENTAL PRODUCT USING THE LILLY PRODUCTION-EXTRACTION METHOD OBTAINED IN THE CLINICAL TRIALS OR OTHER STUDIES OF THIS PRODUCT.

Recently, experimental extract vaccines, simulating this type of acellular pertussis vaccine, were manufactured by Wyeth Laboratories. Clinical studies from two centers comparing two types of the DTP products containing whole cell vaccines were described by Brunell at a workshop on new pertussis vaccines (Brunell 1982) (Attachment 9). Data from one of these centers in 105

children were recently published by Murphy et al. (1983). The authors describe four "notable" reactions. Two children who received extract vaccines experienced episodes of irritability and screaming following the first immunization. These children were given subsequent injections and were reported to be developing normally one year after immunization. A third child receiving an extract vaccine had a temperature of 40°C (104° F) after the third injection. One child given whole-cell vaccine also experienced a temperature of 40°C and was found to have otitis media when examined the day after immunization. These workers reported that no child had a convulsion or shock-like episode. The results of studies with this vaccine performed at the second center and also presented at the workshop have not yet been published. These clinical trials have not demonstrated that the extracted vaccine products are clearly superior to the existing whole-cell vaccines.

(c) IN THE RONNEBERGER AND ZWISLER ARTICLE REFERRED TO BELOW (QUESTION 7a), THE AUTHORS STATE, "DPT-VACCINES WITH WHOLE BACTERIA AS THE ANTIGEN PRODUCED ENCEPHALOMYELITIS IN 57.9% OF THE LEWIS RATS AND 37.0% OF THE WISTAR RATS. AFTER INOCULATION OF EXTRACTED PERTUSSIS ANTIGENS, ONLY 16.4% OF LEWIS RATS AND 5.7% OF WISTAR RATS SHOWED NEUROTOXIC REACTIONS." (P. 182) THIS SEEMS TO SUGGEST THAT EXTRACTED PERTUSSIS VACCINES CAN BE LESS NEUROTOXIC TO MAN THAN WHOLE CELL VACCINES. IN LIGHT OF THIS INFORMATION, PLEASE EXPLAIN WHY YOU THINK THE WYETH EXPERIMENTAL PRODUCT CLINICAL TRIAL DATA DID NOT DEMONSTRATE THAT THIS EXTRACTED VACCINE WAS "SUPERIOR TO THE EXISTING WHOLE CELL VACCINE" FROM THE STANDPOINT OF POTENTIAL REACTOGENICITY/NEUROTOXICITY (ACCORDING TO DR. BRANDT'S JULY 21, 1982, LETTER TO REP. DAN MICA, QUESTION 15)?

Ronneberger and Zwisler reported on the ability of pertussis vaccines to enhance the antigenicity of guinea pig spinal cord, a foreign central nervous system (CNS) tissue, when injected into rats. Reaction against the injected CNS tissue resulted in an experimental allergic encephalomyelitis (EAE). This way of inducing CNS disease experimentally is not a new idea. Use of adjuvants along with neural tissues from a foreign species has been commonly used for many years to study EAE. The Ronneberger and Zwisler article did not deal with direct toxicity of a component of pertussis vaccine on the CNS. The EAE enhancing activity may or may not be related to other biological activity such as potential neurotoxicity. The reduced rate of late weight gain in the mouse weight gain test is the laboratory procedure which correlates with the clinical reactogenicity of pertussis vaccine [for further discussion, see response to question 5(a)]. In the discussion of their publication, Ronneberger and Zwisler state that "The recommended bioassay showed good correlation with the common toxicity tests performed with pertussis vaccines, such as the mouse weight gain test or the leukocytosis tests, and the increase of histamine sensitivity of mice." It is not clear that the procedure they have used has any advantage over the types of tests currently used world wide for this purpose. In addition, we should also note that the extraction procedure used by Ronneberger and Zwisler was not described in their article and it is therefore difficult to make a meaningful comparison between their extract vaccine and that produced by Wyeth.

Finally, as stated in our answer to question 4(b) above, the available clinical data do not support the suggestion that the Wyeth experimental pertussis vaccine was less reactogenic/neurotoxic than whole cell vaccine.

(d) HAS FDA DONE (OR IS FDA AWARE OF) ANY COMPARATIVE RISK-BENEFIT ANALYSIS OF WHOLE CELL PERTUSSIS VACCINES AGAINST EXTRACTED VACCINES? (IF NOT, WHY NOT? IS SUCH A COMPARATIVE ASSESSMENT PLANNED? IF SO, WHAT DID THE ASSESSMENT SHOW?)

See response to questions 4(a) and 4(b) above.

5. IN DR. PETRICCIANI'S NOVEMBER 17, 1982, LETTER TO BARBARA FISHER, VICE PRESIDENT OF DISSATISFIED PARENTS TOGETHER, THE STATEMENT IS MADE THAT, "THERE IS NO LABORATORY PROCEDURE WHICH IS ABLE TO EVALUATE A VACCINE'S TENDENCY TO PRODUCE ABNORMALLY HIGH FEVER, CONVULSIONS, COLLAPSE, EXCESSIVE SCREAMING OR POSSIBLE BRAIN DAMAGE." (PAGE 4).

a. PLEASE EXPLAIN HOW THIS STATEMENT CAN BE RECONCILED WITH (i) THE EXISTENCE OF THE PROPOSED ANIMAL ASSAY PROCEDURE RECOMMENDED FOR PRECLINICAL TESTING OF PERTUSSIS VACCINES IN RONNEBERGER & ZWISLER, "ALLERGIC ENCEPHALOMYELITIS IN RATS--TOXICITY ASSAY FOR PERTUSSIS VACCINES," FURTHER STUDIES IN THE ASSESSMENT OF TOXIC ACTIONS, ARCH. TOXICOL., SUPP. 4, 179-183 (1980); (ii) THE EXISTENCE OF EPA'S NEUROTOXICITY TESTING GUIDELINES UNDER SECTION 4 OF THE TOXIC SUBSTANCES CONTROL ACT; (iii) THE ANIMAL TESTING MODEL/PROCEDURES USED BY STEINMAN, ET. AL., IN "MURINE MODEL FOR PERTUSSIS VACCINE ENCEPHALOPATHY: LINKAGE TO H-2," NATURE, VOL. 299 (OCT. 21, 1982), PP 738-40; (iv) THE EXISTENCE OF THE "OTHER LABORATORY ASSAYS FOR WHOLE CELL PERTUSSIS VACCINE (INCLUDING) A TEST FOR MOUSE LABILE) TOXIN" WHICH ACCORDING TO THE ABOVE REFERENCED LETTER TO MS. FISHER, ARE REQUIRED BY THE JAPANESE GOVERNMENT: AND (v) THE NUMEROUS ANIMAL STUDIES OF FEBRILE SEIZURES, ETC. REFERENCED IN NELSON AND ELLENBERG, FEBRILE SEIZURES, NEW YORK: RAVEN PRESS (1981).

This statement was made because we are still unaware of any tests which are capable of predicting the ability of a vaccine to produce abnormally high fever, convulsions, collapse, excessive screaming, or possible brain damage. Many investigators have tried to define the components of vaccines which might be involved in eliciting such effects. It is known that the vaccine may contain a variety of biologically active substances, such as endotoxin (as do other vaccines derived from gram negative bacteria) and LPF. A variety of procedures have been utilized in many laboratories in an attempt to evaluate the "toxicity" of pertussis vaccines. Several of these tests were used in a recent report by Hooker (J. Biol. Stand. 9: 493-506, 1981). She concluded that based on her evaluation the "seven day weight gain test and the hyperinsulinemia test appeared to be the most sensitive to differences between vaccines." As you know, a mouse weight gain test has been used for measuring the "toxicity" of vaccines in some laboratories for many years. This type of

assay is in use in the U.S. Some workers have shown that vaccines which are more reactive in this assay are associated with more reactions in children, but others have found no such relationship (reviewed by Hooker). This assay is often considered to be measuring the mixtures of toxic materials which may be produced by B. pertussis, including endotoxin and LPF, and it is assays of this type that are used throughout the world by biologics control agencies.

(i). The paper by Ronneberger and Zwisler (1980), as stated in our response to question 4(c), extends the observations previously made by many workers to show that pertussis vaccines when injected along with foreign central nervous system tissue, such as spinal cord, elicit an allergic encephalomyelitis (EAE). As indicated above, these workers have reported that when the neurotoxic activity, as defined by EAE, was compared to the toxicity of a vaccine as evaluated by a mouse weight gain or histamine sensitizing assay, good correlation between tests was obtained. Although this type of assay has been proposed as a tool for assessing the toxicity of pertussis vaccines, we are unaware that any data are available to correlate the results of such a bioassay with the ability to predict the ability of a vaccine to induce neurologic reactions in infants. The correlation of such an assay with neurological events considered to be rare in number would be very difficult to establish.

(ii). The EPA neurotoxicity testing guidelines relate to techniques for developing data on morphologic changes in the nervous system for chemical substances and mixtures subject to such testing under the Toxic Substance Control Act (TOSCA). The types of tests included in these guidelines were specifically tailored to the assessment of toxic substances defined in the Act and are not directly transferable for the purpose of testing pertussis vaccines for their ". . . tendency to produce abnormally high fever, convulsions, collapse, excessive screaming or possible brain damage".

On the other hand, recent research with biological toxins has utilized more specific and sensitive studies at the cellular, subcellular, and molecular levels. Such studies may permit a better understanding of the physical and chemical nature of a toxin, its interaction and effect on host target tissues and eventually may allow the design of specific tests for such toxins. However, it would be necessary to show that such tests correlate with clinical reactions before they would be considered for routine use in control testing of pertussis vaccines.

(iii). The paper by Steinman et al is of course of great interest. However, as indicated in our comments above, we are not aware that any correlation has yet been made between the observations, and the ability of a vaccine to induce severe reactions in children. These authors suggest that their model may provide insight into the pathogenesis of immunization-induced neurological complications. We will be following this work with great interest. However, it should be pointed out that the most effective method for solving the problem of serious adverse reactions probably lies in the development of improved vaccines. (See also our response to question 5(b) below).

(iv). As discussed above, many different laboratory assays have been proposed for evaluating toxicity of vaccines, and different control laboratories in different countries may use different procedures. WHO has recognized (see Requirements for Pertussis Vaccine, Thirtieth Report WHO Expert Committee on Biological Standardization. A.3.4.5. Toxicity Test. 1979) that no single test has been developed which can predict untoward reactions.

The mouse weight gain test is a procedure that assesses the overall effects of endotoxin, LPF, and dermonecrotic toxin. The Japanese government does require other assays for pertussis vaccines which are not required in the United States and we are not aware these are a routine requirement of any other national control authorities testing of pertussis vaccine. Those additional tests done in Japan include a test for mouse-leukocyte increasing toxicity and a test for dermonecrotic (heat labile) toxin. At the time a product license is approved in the United States, evidence is presented to show that the method for inactivation employed by the manufacturer inactivates the dermonecrotic toxin of pertussis vaccine. Pertussis vaccines marketed under U.S. license do not contain biologically active dermonecrotic toxin and this is checked by the absence of early deaths in the mouse weight gain tests done on each vaccine lot. The mouse leucocyte-increasing toxicity test done by the Japanese measures the biological activity of LPF. This activity is measured by the reduced rate of late weight gain in the mouse weight gain test.

(v). The experimental systems described in Febrile Seizures relate to the artificial induction of hyperthermia in animals, and the assessment of subsequent seizures and pathological lesions. We are not aware of information to suggest that if pertussis vaccines were used in those or other animal tests, that any of them could predict the ability of a vaccine to produce abnormally high fever and seizures in humans. As pointed out by Dr. Vannucci in Febrile Seizures,

> "In addition, it is clear that what we do by inducing seizures with fever in animals is vastly different from the situation in human beings, simply because many children manifest their seizures with fever at temperatures much lower than those at which we are able to obtain seizures in animals. Even in the youngest and most susceptible animals, one must induce temperatures well above those seen in the clinical setting.
>
> "Unfortunately, animals do not usually show us a graded range of biological variation in response to different levels of heat. Each species and age seems to develop seizures at a specific level of temperature. Further, seizure-susceptible, inbred strains are vulnerable only to specific stimuli: audiogenic, seizure-susceptible animals do not have seizures easily with fever. So as yet, we do not have a good experimental model of febrile seizures in the animal situation."

The use of limited resources for the development and clinical testing of improved vaccines would seem to be a more productive approach than to divert those resources into research on an animal model for febrile seizures. However, if a test is developed for febrile seizures which does provide good correlations with the human clinical situation, it would be evaluated with respect to its usefulness in testing current or new pertussis vaccines

(b) WHAT RESEARCH, DEVELOPMENT, OR OTHER STUDIES ARE CURRENTLY BEING CONDUCTED BY, SUPPORTED BY, OR PLANNED BY HHS (FDA?, CDC? NIH? OTHER?) TO DEVELOP AN ANIMAL TEST PROCEDURE WHICH CAN BE USED EFFECTIVELY AS A PRELINICAL SCREENING MECHANISM TO DETECT VACCINE LOTS WHICH TEND TO BE MORE NEUROTOXIC/POTENTIALLY REACTOGENIC?

The agency uses animal models such as lymphocytosis in mice and histamine sensitization in its evaluation of purified antigens and in its experimental programs of evaluation of LPF antigen content of vaccines (see transcript of Workshop 1982). These assays are being used to evaluate the bioactivity of antigens which might be considered protective antigens.

The work of Steinman et al., was supported in part by an NIH grant (NS 18235-01). Researchers from England have begun studies of children who develop complications from pertussis vaccine. They hope to identify a genetic marker in humans which may help to identify a subpopulation of children who are at greater risk to reactions to the vaccine. The feasibility of conducting retrospective or prospective HLA studies in humans in the United States is under review by NIAID.

(c) WHAT CURRENT PLANS DOES HHS HAVE TO REQUIRE LICENSED MANUFACTURERS TO UTILIZE ONE OR MORE LABORATORY TEST PROCEDURES FOR EVALUATING A PERTUSSIS VACCINE'S POTENTIAL NEUROTOXICITY/REACTOGENICITY (OTHER THAN THE MOUSE WEIGHT GAIN PROCEDURE WHICH ADMITTEDLY IS INADEQUATE FOR THE ABOVE PURPOSE)? WHAT CURRENT PLANS DOES HHS HAVE TO CONDUCT SUCH TESTING ITSELF?

See comments under (a)(iv) above. At the present time, HHS has no plans to require licensed manufacturers to include additional tests for licensed whole cell vaccines.

As new scientific information is developed, FDA would consider performing additional assays on licensed products, and if there were a consensus that they were meaningful, they would be proposed as new requirements.

6. IN DR. PETRICCIANI"S LETTER TO MS. FISHER REFERRED TO ABOVE, THE ANSWER TO QUESTION 21 WAS AS FOLLOWS: TITLE 21 OF THE CODE OF FEDERAL REGULATIONS, SECTION 211.198 REQUIRES THAT MANUFACTURERS HAVE WRITTEN PROCEDURES DESCRIBING THE HANDLING OF WRITTEN AND ORAL COMPLAINTS. BOTH THE OB AND THE CENTERS FOR DISEASE CONTROL RECEIVE REPORTS OF ADVERSE REACTIONS. THE NATURE OF THEIR RESPONSE IS BASED ON AN EVALUATION OF THE REPORTED REACTIONS."

(a) PLEASE PROVIDE A COPY OF EACH OF THE WRITTEN PROCEDURES ADOPTED BY WYETH, LEDERLE, AND CONNAUGHT IN CONFORMANCE WITH 21 CFR 211.198.

The provisions of 21 CFR 211.198 are part of the Good Manufacturing Practices for Human and Veterinary Drugs with which manufacturers of licensed biological products must comply. It was the intent of the agency when these regulations were promulgated to provide manufacturers with as much latitude as possible for efficient review of the drug product complaints. Thus, the manufacturers are responsible for the development of their own internal written standard operating procedures in conformance with the requirements of 21 CFR 211.198. Manufacturers are not required to submit copies of their written procedures for handling oral and written complaints.

(b) WERE THESE PROCEDURES REVIEWED AND APPROVED BY FDA? (IF SO, WHEN? IF NOT, WHY NOT?);

The written procedures are reviewed as part of the FDA inspection of licensed manufacturers. Inspectors examine the procedures for adequacy in terms of completeness, timeliness and follow-up action on all oral and written complaints received. Any significant deficiencies are brought to the attention of the responsible head of the establishment.

(c) WHAT SYSTEMS, TECHNIQUES, OR APPROACHES DOES FDA USE TO ASSURE THAT THE COMPANY'S PROCEDURES FOR RESPONDING TO COMPLAINTS AND ADVERSE REACTION REPORTS ARE FULLY IMPLEMENTED AS WRITTEN?

As indicated in accordance with Title 21 of the Code of Federal Regulations, section 211.198, the manufacturer must establish and follow written procedures describing the handling of all written and oral complaints regarding a drug product. A written record of each complaint is maintained in a file designated for drug product complaint. The file should include the following information, where known: the name and strength of the product; lot number; name of complainant; nature of complaint; and reply to complainant. When an investigation of the product records is conducted, the written record should include the findings of the investigation and follow-up. When an investigation of the production records is not conducted, the written record should include the reason that an investigation was found not to be necessary and the name of the responsible person making the determination. The manufacturers are inspected on a routine basis and the complaint files are required to be readily available for inspection. The inspector can observe the implementation of the manufacturer's written procedures for handling complaints.

(d) IS THE FDA AWARE OF ANY INFORMATION THAT THESE PROCEDURES ARE NOT BEING/OR HAVE NOT BEEN FOLLOWED IN ANY CASE? IF SO, PLEASE PROVIDE THAT INFORMATION?

An extensive search of the inspection files for each biologic product manufacturer would be necessary to determine whether or not firms were ever found to be deficient in a particular area of the regulations.

A search of the inspection files for the last 5 years (1978-present) for the three companies listed in question 6(a) failed to reveal any reported deficiencies in the manner in which they handle complaints.

(e) IS THE FDA CONSIDERING EITHER REVISING SECTION 211.198 TO REQUIRE MORE EXTENSIVE FOLLOW-UP BY MANUFACTURERS IN CASES INVOLVING REPORTS OF ANY OF THE REACTIONS LISTED IN QUESTION 1 (ABOVE) OR REQUIRING REVISION OF THE WRITTEN PROCEDURES WITHOUT ANY CHANGE IN THE REGULATIONS TO ASSURE MANUFACTURER TRACKING AND RECORDKEEPING OF SIGNIFICANT POST-REACTION SEQUELLAE?

At this time, FDA is not planning to revise section 211.198, nor are we considering requiring revisions without a change in the regulations.

7. IS THE HHS DEPARTMENT CONSIDERING ATTEMPTING TO DEFINE CATEGORIES OF POTENTIALLY HIGH RISK CHILDREN (I.E., POTENTIALLY AT HIGHER RISK OF SIGNIFICANT ADVERSE REACTION TO PERTUSSIS VACCINATION THAN CHILDREN IN THE NORMAL POPULATION) FOR THE PURPOSE OF PROVIDING ADDITIONAL INFORMATION AND GUIDANCE TO PHYSICIANS, STATE AND LOCAL HEALTH DEPARTMENTS, PUBLIC HEALTH CLINICS, ETC.?. . .

HHS is interested in identifying factors which might predict significant adverse reactions to pertussis vaccination. As indicated in Section 3 of the report to Senator Hawkins, we are currently reviewing policies and recommendations from other countries and consulting the medical literature with regard to current contra-indications. Individual reaction reports in HHS or manufacturer files have been considered in determining contraindications in the past; use of this source of information will be continued. The MSIFI system in particular is just now getting systematized. Such reports will be a part of further considerations. Followup of all reports of neurological events reported following vaccination will provide additional information about pre-existing conditions which is not present on the current report forms. We would be pleased to receive reports of reactions discovered in letters from parents and include these in the considerations. The Department's approach to arriving at definitions of contraindications and precautions is through consultation with a variety of groups, including but not limited to the Immunization Practices Advisory Committee (ACIP)and FDA's Vaccine Advisory Committee. Meetings of these committees are open to the public and announced in the Federal Register. The basis for the current recommendations of the Department of Health and Social Security, United Kingdom, and those of the ACIP and the AAP are under review by CDC. The results of this review are to be presented to the ACIP at its meeting on October 18-19, 1983.

9. IN DR. BRANDT"S LETTER TO REP. MICA (REFERRED TO ABOVE), THE FOLLOWING QUESTION AND ANSWER WAS INCLUDED:

"SHOULD PARENTS HAVE A CHOICE AS TO WHETHER TO GIVE THE [PERTUSSIS] SHOT?"

"WE URGE THAT HEALTH CARE PROVIDERS DISCUSS THE RISKS AND BENEFITS OF ALL VACCINATIONS WITH PARENTS."

(a) SPECIFICALLY, WHAT STEPS HAS HHS TAKEN TO "URGE" HEALTH CARE PROVIDERS TO DISCUSS RISKS AND BENEFITS OF PERTUSSIS VACCINATION WITH PARENTS? DOES THE DEPARTMENT HAVE ANY EMPIRICAL EVIDENCE, STUDIES, OR OTHER PROOF THAT THESE STEPS TO URGE DOCTOR-PARENT DISCUSSION OF RISKS AND BENEFITS PRIOR TO VACCINATION IS WORKING IN FACT, I.E., THAT HEALTH CARE PROVIDERS ARE ENGAGING IN DETAILED DISCUSSIONS OF VACCINE RISKS AND BENEFITS WITH PARENTS BEFORE CHILDHOOD IMMUNIZATIONS?

HHS sponsored a survey of public attitudes and practices towards immunizations in 1979. This indicated that, of families in which children had received DTP vaccination in the preceding 12 months, 43 percent had had information presented to them about risks and benefits and 33 percent had signed a form. This survey also indicated that 3 percent of children who had received DTP in the past year had a reaction that required a visit to a doctor, hospital, or clinic.

HHS through its publications and presentations, and recommendations of the ACIP, urges all health-care providers to discuss risks and benefits of all vaccinations with the recipients or their parents. The "General Recommendations on Immunization" of the ACIP state: "Parents and patients should be informed about the benefits and risks of vaccines. It is essential that the patient or the responsible person be given information concerning the risks of vaccines as well as the major benefits from vaccines in preventing disease in both individuals and the community. Benefit and risk information should be presented in terminology that is as simple as possible. No formal and legally acceptable statement has been universally adopted for the private medical sector. CDC has developed 'Important Information Statements' for use with federally purchased vaccines given in public health clinics. Practitioners may wish to consider these or similar materials for parents and patients. The Committee recommends that there be ample opportunity for questions before each immunization." Increased provider-parent dialogue regarding risks of disease, risks and benefits of vaccine, and the recognition and reporting of any adverse event are recommended for discussion during these question periods.

(d) WHAT PLANS, IF ANY, DOES HHS HAVE TO IMPROVE THE IMPORTANT INFORMATION FORM AND TO ASSURE ADEQUATE WRITTEN PARENT INFORMATION IS PROVIDED ON THE RISKS AND BENEFITS OF PERTUSSIS VACCINATION BY BOTH PRIVATE PRACTITIONERS AND PUBLIC CLINICS?

Important information forms for all childhood vaccines have been in use since 1977-1978. They were revised in 1979-1980 and have been in a further process of revision since October of 1982. Revised forms are now available and being distributed to State and local health departments. It is anticipated they will go into widespread use approximately by August 1, and into exclusive use by October 1, 1983. To assure that important information statements are being properly used, each grantee is required to address the issue of important information forms on a quarterly basis; and on each field visit to conduct reviews of immunization programs, the use of important information forms is specifically addressed. At this moment, there is no mechanism envisioned which could assure adequate information is provided in private practitioners' offices.

(e) WHAT PLANS, IF ANY, DOES HHS HAVE TO ASSURE ADEQUATE WRITTEN PARENT INFORMATION IS PROVIDED ON MONITORING OF CHILDREN RECEIVING PERTUSSIS VACCINE, ON CONTRAINDICATIONS AND HIGH RISK CONDITIONS, ON PREVENTIVE MEASURES PARENTS CAN TAKE TO MINIMIZE THE RISKS OF SERIOUS ADVERSE REACTIONS, ON PARENTS' RIGHT TO REPORT ADVERSE REACTIONS, ETC., BY BOTH PRIVATE PHYSICIANS AND PUBLIC CLINICS?

See response to item d. The Important Information forms specifically request that parents report adverse reactions to the local health departments. The portion of the Important Information form requesting this report contains a telephone number to receive the report and is given to the parent to take home.

(f) WOULD THE DEPARTMENT FAVOR LEGISLATION TO REQUIRE THAT WRITTEN RISK AND BENEFIT INFORMATION, AND INFORMATION OF THE TYPES REFERRED TO IN QUESTION 9(e) IS PROVIDED TO PARENTS BY PRIVATE OR PUBLIC HEALTH CARE PROVIDERS PRIOR TO PERTUSSIS VACCINATION?

We believe the current mechanism is adequate to assure use of the Important Information forms in the public sector. The Department also feels that legislation would not necessarily assure their use in the private sector.

10. PLEASE STATE WHETHER OR NOT HHS FAVORS OR OPPOSES STATE LAWS WHICH AUTHORIZE AN EXEMPTION FROM MANDATORY VACCINATION REQUIREMENTS BECAUSE OF "PHILOSOPHICAL OBJECTION" OR "PERSONAL CONVICTION"? WHY DOES THE DEPARTMENT TAKE THIS POSITION? DOES THE DPEARTMENT FAVOR OR OPPOSE A "RELIGIOUS OBJECTION" EXEMPTION FROM MANDATORY VACCINATION? WHY? IF THE "RELIGIOUS" AND "PHILOSOPHICAL/PERSONAL" OBJECTIONS ARE NOT EITHER BOTH SUPPORTED OR BOTH OPPOSED BY HHS, PLEASE EXPLAIN THE REASONS FOR TAKING A DIFFERENT POSITION ON THE ONE TYPE OF OBJECTION THAN ON THE OTHER.

HHS neither favors nor opposes philosophical objection nor personal conviction exemptions from mandatory vaccination requirements. The model school immunization law drafted by the Centers for Disease Control and distributed in February 1981 provided for religious and medical exemptions but not for personal or philosophical exemptions. Religious exemptions have been a traditional part of immunization requirements. However, courts in at least two States (Arkansas, Maryland) have struck down religious exemptions in recent years. An important reason for not vigorously supporting personal/philosophical exemptions has been a feeling that it is likely many parents would choose to claim such exemptions rather than go to the trouble of locating immunization records or (if their child needed them) obtaining needed immunizations.

11. PLEASE INDICATE ON A STATE-BY-STATE BASIS WHETHER THE INCIDENCE OF WHOOPING COUGH (REPORTED AND BACTERIOLOGICALLY CONFIRMED) INCREASED AFTER ADOPTION BY EACH STATE WHICH HAS DONE SO OF A "PERSONAL CONVICTION" OR "PHILOSOPHIC OBJECTION" EXEMPTION FROM MANDATORY PERTUSSIS VACCINATION? IF SO, BY WHAT PER CENT ON A PER CAPITA BASIS DID THE DISEASE INCREASE?

Data are not available which would permit analysis of incidence of pertussis before and after adoption of personal/philosophical exemptions from mandatory immunization. It should be noted that States which allow personal/philosophical exemptions do so generically, rather than for any specific immunization alone.

(a) IS THERE ANY SIGNIFICANT DIFFERENCE ON A PER CAPITA BASIS IN THE WHOOPING COUGH INCIDENCE RATE (REPORTED AND CONFIRMED) BETWEEN STATES WHICH PERMIT SUCH EXEMPTIONS AND STATES WHICH DO NOT?

There are six States which do not require pertussis immunization for school entrance (Arizona, Kentucky, Missouri, New York, Pennsylvania, Rhode Island). In 1982 the provisional pertussis incidence rate in those States was 1.394 cases per 100,000. Sixteen States which require pertussis vaccination allow personal or philosophical exemptions for immunizations (California, Colorado, Delaware, Idaho, Louisiana, Maine, Michigan, Minnesota, Montana, North Dakota, Ohio, Oklahoma, Utah, Vermont, Washington, Wisconsin). The provisional pertussis rate in those States in 1982 was 0.63 cases per 100,000. The remainder of States require pertussis immunization and do not permit personal/philosophical exemptions. The provisional pertussis rates in those States is 0.66. The difference in incidence rate between States which do not require pertussis at all and those which do is significant. There is no significant difference in the reported pertussis incidence rate in States which require pertussis immunization and allow personal/philosophical exemptions as compared with those which require pertussis immunization and do not allow such exemptions.

(b) ON A STATE-BY-STATE BASIS, HOW MANY EXEMPTIONS HAVE BEEN REQUESTED ON THE "PERSONAL CONVICTION" OR "PHILOSOPHIC OBJECTION" GROUNDS SINCE 1970?

Data are not available to permit a response to this question since this information is not systematically reported to CDC. However, data from the States which do report such information to CDC indicate that less than 1 percent of students have personal or philosophical exemptions.

(c) HAS THE ANNUAL NUMBER OF EXEMPTION REQUESTS INCREASED SINCE APRIL 1982? BY HOW MANY?

No data exist to answer this question.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Centers for Disease Control
Atlanta, Georgia 30333

August 4, 1983

Mr. Jeffrey Schwartz
Dissatisfied Parents Together
Box 563, 1377 K Street, NW
Washington, D.C. 20005

Dear Mr. Schwartz:

Enclosed are answers from FDA to questions 8, 9 and 12 contained in your letter of April 29. This, along with our answers of July 20, completes our response.

Sincerely yours,

Walter R. Dowdle, Ph.D.
Director, Center for Infectious Diseases
and
Chairman, Interagency Group to Monitor
Vaccine Development, Production and Usage

Enclosure

8. IN DR. BRANDT'S LETTER TO REPRESENTATIVE MICA (REFERRED TO ABOVE), THE FOLLOWING QUESTION AND ANSWER WAS INCLUDED:

"20. DO YOU THINK THAT REACTIONS TO PERTUSSIS VACCINE SHOULD BE A MANDATORY REPORTING ELEMENT FOR DOCTORS?"

"WE BELIEVE THAT SEVERE OR UNEXPECTED REACTIONS TO ANY VACCINE SHOULD BE REPORTED BY PHYSICIANS. IT IS UNLIKELY THAT EVEN IF MANDATED, THIS COULD SATISFACTORILY BE IMPLEMENTED."

(a) DOES FDA/HHS/CDC HAVE THE AUTHORITY EITHER DIRECTLY OR INDIRECTLY UNDER EXISTING LEGISLATION TO MANDATE SUCH REPORTING BY PRIVATE PHYSICIANS? IF NOT, WOULD FDA/HHS FAVOR LEGISLATION TO CONFER UPON IT SUCH AUTHORITY OR TO DIRECTLY REQUIRE SUCH REPORTING? (IF NOT, WHY NOT?)

The types of recordkeeping and adverse reaction reporting requirements that you have inquired about are the type of requirements that would normally be imposed under the current good manufacturing practices (CGMP's) provisions of the Federal Food, Drug, and Cosmetic Act ("FDC Act"). Biological products are drugs and as such are required to be manufactured in accordance with CGMP's. However, the CGMP requirements do not apply to the practice of medicine. We can and do impose these types of recordkeeping requirements on manufacturers, processors, and packers of drug products, but do not have authority to impose similar requirements on physicians. Nor would it appear that other provisions of the FDC Act or the Public Health Service Act would provide such authority.

In regard to the second part of your question, FDA/HHS believes that requiring mandatory reporting of adverse reactions by physicians would be a significant additional burden, would be difficult to enforce, and thus would be regarded as controversial. In view of the current efforts to address the problem of adverse reaction reporting alluded to elsewhere in our response, we believe that it would be premature to foster such legislation without further careful deliberation and discussion of the matter with outside advisory groups. It should also be noted that such a requirement would likely incur significant costs for providing for the review of this additional information and for enforcement.

Most current reporting systems concerned with the occurrence of diseases or of adverse reactions are voluntary. Under these systems, underreporting is a common feature. Nonetheless, such systems provide useful data concerning trends in frequency of the observed events which are of epidemiologic value even in the absence of the reporting which is 100% complete.

(b) DOES FDA/HHS/CDC HAVE THE AUTHORITY UNDER EXISTING LAW TO REQUIRE THE MANUFACTURER OF A LICENSED PERTUSSIS VACCINE TO INCLUDE AS AN EXPRESS CONDITION OF ITS CONTRACT OF SALE TO ANY PURCHASER OF THE VACCINE THAT THE PURCHASER SHALL REPORT ALL SEVERE REACTIONS OF WHICH IT BECOMES AWARE TO THE CDC AND SHALL REQUIRE IDENTICAL PROVISIONS TO BE EXPRESSLY INCLUDED AS A CONDITION OF ALL SUBSEQUENT SALES OF THE

VACCINE? IF SO, IS FDA CONSIDERING IMPLEMENTING THIS AUTHORITY? (IF NOT, WHY NOT?) IF FDA/HHS/CDC DOES NOT HAVE THE ABOVE AUTHORITY UNDER EXISTING LAW, WOULD FDA/HHS/CDC FAVOR LEGISLATION TO CONFER UPON IT SUCH AUTHORITY?

As noted above, FDA does not have authority to directly require physicians to report adverse reactions. It is therefore doubtful that FDA could do indirectly, i.e., by requiring manufacturers to contractually impose reporting requirements upon physicians, what it cannot do directly. Moreover, even if FDA could require such a contractual provision, enforcement of the provision would be very difficult. FDA could not inspect physicians' offices, nor could FDA take any action against a physician who failed to make such reports. As discussed above, FDA believes that a voluntary physician-adverse reaction reporting system is appropriate.

(c) HOW SHOULD "SEVERE OR UNEXPECTED" REACTIONS BE DEFINED FOR REPORTING PURPOSES ONLY?

Severe or unexpected reactions could be defined to include an event which is either:

1. not reported in the direction circular;
2. potentially life-threatening/fatal;
3. permanently disabling;
4. requires hospitalization for treatment;
5. requires extensive therapy for treatment; and/or
6. takes longer than 15 days for recovery.

(d) SAME QUESTIONS AS (a) AND (b) ONLY WITH RESPECT TO THE AUTHORITY TO REQUIRE DIRECTLY OR INDIRECTLY WRITTEN RECORDKEEPING BY THE ADMINISTERING PERSON OF THE MANUFACTURER'S NAME AND LOT NUMBER OF DATE OF ADMINISTRATION FOR EACH VACCINATION CONTAINING PERTUSSIS?

FDA probably could not require manufacturers to make physicians keep records.

(e) WOULD HHS/FDA/CDC FAVOR GIVING DIRECT INFORMATION TO PARENTS ON THEIR RIGHT TO FILE ADVERSE REACTION REPORTS DIRECTLY WITH CDC? WOULD HHS/FDA/CDC FAVOR REQUIRING PHYSICIANS TO NOTIFY PARENTS OF THIS RIGHT IN WRITING. WHY OR WHY NOT?

Parents of children given DTP, measles-mumps-rubella and poliovirus vaccines in public programs already receive an "information form which solicits reports of reactions occurring within four weeks of immunization to a responsible individual." This information regarding significant reactions is then relayed to CDC. The American Academy of Pediatrics Committee on Infectious Diseases (the "Redbook" Committee) has reprinted these forms in their latest Report

(1982) and has indicated that, "...practitioners should consider the use of these or similar materials for parents and patients...." The physician may report reactions to either the manufacturer, the USP, or to FDA directly.

Although encouraging physicians to notify parents of their right to report adverse reactions might result in more reported adverse reactions, FDA does not have authority to require that they distribute the information.

(f) WHAT IS HHS/FDA/CDC DOING AND PLANNING TO DO TO ENCOURAGE PRIVATE PHYSICIAN REPORTING OF SEVERE ADVERSE REACTIONS?

The FDA encourages private physicians to report severe adverse reactions as follows:

i. A Drug Experience Report Form (FDA 1639) is provided to approximately one and one-half million health professionals with the FDA Bulletin.

ii. The FDA sponsors an exhibit featuring adverse reaction reporting at various health professional meetings. Individuals are encouraged to report reactions and the procedures for submitting reports are explained.

iii. The majority of reports from individuals are acknowledged by FDA in the form of a phone call or letter. Reporters are thanked for submitting the report and are encouraged to report further reactions.

iv. The Drug Experience Report Form is provided in tear-out form in the AMA Drug Evaluations, published by the American Medical Association in 1983. Physicians are encouraged to report reactions in the section on adverse reactions. This form is also included periodically in the "FDA Drug Bulletin".

9. IN DR. BRANDT'S LETTER TO REPRESENTATIVE MICA (REFERRED TO ABOVE) THE FOLLOWING QUESTION AND ANSWER WAS INCLUDED:

"SHOULD PARENTS HAVE A CHOICE AS TO WHETHER TO GIVE THE (PERTUSSIS) SHOT?"

"WE URGE THAT HEALTH CARE PROVIDERS DISCUSS THE RISKS AND BENEFITS OF ALL VACCINATIONS WITH PARENTS."

(b) SHOULD VACCINE MANUFACTURERS BE REQUIRED TO PROVIDE WRITTEN RISK AND BENEFIT INFORMATION DIRECTLY TO PARENTS PRIOR TO VACCINATION? WHY OR WHY NOT? DOES THE DEPARTMENT HAVE THE LEGAL AUTHORITY UNDER EXISTING LAW TO PRESCRIBE AND ENFORCE SUCH A REQUIREMENT?

Biological products, such as vaccines, are drugs and are subject to the labeling requirements of the Federal Food, Drug, and Cosmetic Act (FDA Act). Section 502 (a) of the FDC Act prohibits false or misleading labeling. FDA has determined that, without a patient package insert, the labels of certain prescription drugs are misleading because they fail to reveal facts about the consequences that may result from the use of the drugs. This position was

upheld in Pharmaceutical Manufacturers Ass'n v. FDA, 634 F. 2d 106 (3rd Cir., 1980). Although FDA could require manufacturers to provide to physicians a patient package insert with each dose of vaccine, FDA could not compel physicians to provide this information to their patients. The information provided to a patient about the risks and benefits of a drug is considered to be the practice of medicine and is not an area that FDA regulates.

(c) SHOULD PERTUSSIS VACCINE MANUFACTURERS BE REQUIRED TO INCLUDE IN ITS SALE CONTRACT A PROVISION SUCH AS THAT STATED IN QUESTION 8(b), EXCEPT WITH RESPECT TO THE PROVISION TO EACH PURCHASER OF THE VACCINE (INCLUDING THE ULTIMATE USER--THE PARENT OF THE VACCINEE) OF ADEQUATE WRITTEN INFORMATION ON THE BENEFITS AND RISKS OF THE VACCINE? WHY OR WHY NOT? DOES FDA/HHS HAVE THE AUTHORITY UNDER EXISTING LAW TO IMPOSE SUCH A REQUIREMENT AS A CONDITION OF LICENSURE OR OTHERWISE?

See answer to question 8(b). Although FDA does not have authority to mandate such a requirement, the committee believes that benefit and risk information should be presented to patients and parents. See answer to question 9(a).

12. IN DR. BRANDT'S ANSWER TO REPRSENTATIVE MICA's QUESTION #4, IT IS STATED THAT "LICENSURE [OF THE JAPANESES ACELLULAR PERTUSSIS VACCINE] FOR WIDE-SCALE USE [IN THE UNITED STATES] WILL TAKE SEVERAL YEARS."

(a) WHY IS THIS SO? SPECIFICALLY, WHAT STEPS HAVE TO BE TAKEN (AND WHAT SPECIFIC CRITERIA MET) FOR THIS NEW VACCINE TO QUALIFY FOR LICENSURE?

The requirements for filing and obtaining approval to market a new vaccine in this country are the same for all manufacturers. Each manufacturer is required to file an establishment license application describing the facilities used to manufacture the vaccine and a product license describing the method of production as well as the tests and data to demonstrate the safety, purity, potency and effectiveness of the product. In addition, each manufacturer must develop standardized laboratory tests in order to assure batch-to-batch consistency and to provide a basis for establishing the dating period for the product.

(b) HOW LONG APPROXIMATELY SHOULD EACH STEP TAKE?

It should be noted that as of this response, no license application for a Japanese or Japanese-type pertussis vaccine has been received by the Office of Biologics. Until an application has been received and reviewed, it is very difficult to predict with any accuracy the time required for licensing. However, as an example, the development and initiation of a clinical field trial followed by the review and analysis of the data collected may take two to three years depending upon the availability of a suitable population to conduct the trials and the criteria (protocol) for establishing the safety and efficacy parameters.

(c) ARE THESE REQUIREMENTS AND CRITERIA MORE STRINGENT THAN THE LICENSURE REQUIREMENTS AND CRITERIA WHICH HAVE BEEN APPLIED TO THE WHOLE CELL PERTUSSIS VACCINES NOW IN USE IN THE UNITED

STATES? IF SO, IN WHAT RESPECTS? ARE THESE REQUIIREMENTS AND CRITERIA MORE STRINGENT THAN THOSE APPLIED TO ELI LILLY'S TRISOLOGEN PRODUCT? IF SO, IN WHAT RESPECTS?

Since the initial licensure of some of the whole cell pertussis vaccines was over thirty years ago, it is reasonable to expect that the requirements and criteria for licensure are more stringent today for any new vaccine intended to be introduced for marketing in the United States. Today we would require substantial evidence of the safety and effectiveness of the vaccine, additional laboratory testing to characterize the vaccine, and greater manufacturing controls over the production of the vaccine. Since Lilly's Trisologen/TM was approved for marketing in the 1960's, today's requirements and criteria would be more stringent as explained above.

(d) IN THE DEPARTMENT'S VIEW IS IT IN THE PUBLIC INTEREST TO APPLY MORE STRINGENT STANDARDS AND TESTS FOR LICENSURE OF NEW VACCINES THAT HAVE SHOWN THEY CAN MEET STANDARDS AND TESTS WHICH APPLIED AT THE TIME OF LICENSURE (AND LICENSE REVIEW) OF CURRENT VACCINES, IF SUCH TESTS SHOW THE NEW VACCINES TO BE SUBSTANTIALLY LESS REACTOGENIC/NEUROTOXIC THAN THE CURRENTLY LICENSED VACCINES?

Many of the standards and tests which would apply to a new pertussis vaccine are already established in the Code of Federal Regulations (CFR). The decision on whether or not to license a new pertussis vaccine depends not only on its degree of reactogenicity and neurotoxicity, but on other key factors such as its efficacy. A new vaccine submitted for licensure might well demonstrate a very low level of reactogenicity, for example, but fail to be efficacious. We would therfore expect a new pertussis vaccine, as a minimum, to meet the current standards for safety, purity, potency, and efficacy. If, however, data were developed to show that the safety and efficacy standards already established in the CFR were not appropriate for a particular new vaccine, FDA would establish a standard for that vaccine.

(e) WHAT INFORMATION DOES THE DEPARTMENT HAVE (OR KNOW OF) CONCERNING THE (i) POTENCY OF THE JAPANESE ACELLULAR VACCINE; (ii) THE ABILITY OF THE JAPANESE ACELLULAR VACCINE TO PASS THE MOUSE WEIGHT GAIN TEST; (iii) THE REACTOGENICITY/NEUROTOXICITY OF THE JAPENESE ACELLULAR VACCINE, AS MEASURED BY APPLICABLE JAPANESE TESTS: (iv) THE CLINICAL EXPERIENCE IN JAPAN (OR ELSEWHERE) WITH THE VACCINE'S POTENCY AND REACTOGENICITY/NEUROTOXICITY? PLEASE PROVIDE AS MUCH OF THIS INFORMATION AS IS CURRENTLY AVAILABLE?

FDA obtained samples of the Japanese acellular pertussis vaccine from the Japanese National Institute of Health (NIH) pursuant to an agreement that FDA would not release any information concerning the vaccine without the consent of the Japanese government. FDA has conducted laboratory tests on these vaccines, but considers this information confidential because of the agreement with the Japanese government.

To our knowledge, the Japanese vaccine has not been used outside of Japan. Preliminary clinical results with the acellular vaccine in Japan were reported by Professor Kimura in the workshop on "New Pertussis Vaccines-- Laboratory and Clinical Evaluation." No published clinical results detailing the clinical safety, potency, and/or evidence of clinical efficacy of the acellular vaccine pertussis vaccine are available.

(f) WHAT STEPS, IF ANY, IS THE DEPARTMENT PLANNING TO TAKE TO EXPEDITE, OR ENCOURAGE EXPEDITION OF, TESTING AND LICENSURE OF THE JAPANESE ACELLUALR VACCINE? WHEN DOES THE DEPARTMENT PLAN TO TAKE THESE STEPS?

The ultimate decision of whether or not to submit a new pertussis vaccine to FDA for licensure rests with the manufacturers. However, FDA has indicated its interest in the evaluation of the current Japanese vaccine or a Japanese-like vaccine. Discussions have been held with each of the three major manufacturers to encourage them to pursue an acellular pertussis vaccine. In addition, FDA has been in contact with the Japan National Institute of Health (NIH) regarding samples of the Japanese vaccine for both clinical and laboratory testing. Because of liability concerns, the Japanese have restricted our use of any samples which they might supply to us for laboratory evaluation only. Each of the U.S. commercial manufacturers of pertussis vaccine has stated that they have ongoing efforts to develop an improved vaccine. In anticipation of the submission of a Japanese-like acellular vaccine for licensure, as noted above, FDA has done some laboratory tests with samples supplied by the Japan NIH. As a followup, the Japanese have sent FDA 300 mL samples from each of five additional lots of pertussis vaccine for laboratory testing; these tests are in progress. FDA is prepared to conduct laboratory testing of experimental lots of new pertussis vaccine candidates as soon as they are developed.

LITERATURE REVIEW ON SELECTED CONTRAINDICATIONS TO PERTUSSIS VACCINE

Some infants should not receive the pertussis vaccine at all, in light of existing knowledge about contraindications. Others will react to the first (or later) shot severely enough to warn the physician against administering any further pertussis vaccine. According to the following sources in the medical literature on pertussis vaccination, the pertussis vaccine is generally contraindicated when one or more of the following conditions exists:

1. **A personal history of convulsions or neurologic disease.**

   The following sources state a personal history of convulsions or neurologic disease is a contraindication (i.e. to the first shot):

   1. Brody, M.: Neurologic complications following administration of pertussis vaccine. Brooklyn Hospital Journal 5:107-113, 1947

   2. Toomey, J.A.: Reactions to pertussis vaccine. JAMA 139:7:448-450, 1949

   3. Cockburn, W.C.: Whooping Cough Immunization. The Practitioner 167: 232-236, 1951

   4. Sutherland, J.M.: Encephalopathy following diptheria-pertussis inoculation. Arch Dis Child 28:138:149-150, 1953

   5. Immunization in Young Children: Br Med J 1045-1046, 1953.

   6. Medical Research Council: Vaccination against whooping cough. Br Med J 2:454-462, 1956

   7. Forfar, J.O. and Arnell, G.C., Ed.: Textbook of Pediatrics. Churchill-Livingstone, 1973

   8. Merrill-National Laboratories, Inc.: Diptheria and Tetanus Toxoids and Pertussis Vaccine Adsorbed U.S.P. (P-T-D, A-P, National) Product Information July, 1974

   9. Vaccination Against Whooping Cough. Br Med J 5930: 539-540, 1974

   10. Griffeth. A.: Pertussis vaccine and convulsive disorders of childhood. Proc roy Soc Med 67:5:16, 1974

   11. Kulenkampff, M. et al: Neurological complications of pertussis inoculation. Arch Dis Child 49:46-49, 1974

   12. Immunization Against Whooping Cough. WHO Chron 29:365-367, 1975

   13. Griffeth, A.: Reactions after pertussis vaccine: a manufacturer's experiences and difficulties since 1964. Br Med J 1:809-815, 1978

   14. Valman, H.B.: Contraindications to Immunization. Br Med J 1138-1139, 1980

   15. Lederle Laboratories Division, Inc.: Diptheria and Tetanus Toxoids and Pertussis Vaccine Adsorbed Tri-immunol Product Information February, 1980

16. Robinson, R.J.: The whooping cough immunization controversy. Arch Dis Child 56: 577-580, 1981

17. Miller, D.L. et al: Pertussis immunization and serious acute neurological illness in children. Br Med J 1595-1599, 1981

Case histories and data presented in the following sources give additional evidence that children with a history of convulsions or neurologic disease should not receive the pertussis vaccine (i.e. the first shot):

18. Byers, R. and Moll, F.C.: Encephalopathies following prohylactic pertussis vaccine. Pediatrics 1:437-456, 1948

19. Hopper, J: Illness after whooping cough vaccination. The Medical Officer 106: 24-244, 1961

20. Hannik, C.A.: Major reactions after DPT-Polio vaccination in the Netherlands. Symp Series Immunobiol Standard 13:161-170, 1970

21. Stewart, G.T.: Toxicity of pertussis vaccine: frequency and probability of reactions. J Epidemiol Community Health 33:150, 1979

In addition to the above 21 references, the following sources specify that a history of convulsions following the DPT shot is a contraindication to future shots of pertussis vaccine:

22. Melin, K.: Pertussis immunization in children with convulsive disorders. J Pediatr 43: 652-654. 1953

23. Strom, J.: Is universal vaccination against pertussis always justified? Br Med J 2:1184-1186, 1960

24. Strom, J.: Further experiences of reactions, especially of a cerebral nature, in conjunction with triple vaccination: A study based on vaccinations in Sweden 1959-65. Br Med J 320-323, 1967

25. Connaught Laboratories, Inc.: Diptheria and Tetanus Toxoids and Pertussis Vaccine Adsorbed USP Product Information July, 1980

26. Harrison, H. and Fulginiti, V.: Bacterial Immunizations. Am J Dis Child 134, 1980

27. Immunization Practices Advisory Committee (ACIP): Diptheria, Tetanus and Pertussis: Guidelines for Vaqcine Prophylaxis and Other Preventive Measures. MMWR 30:32:392-403, 1981

28. Wyeth Laboratories, Inc.: Diptheria and Tetanus Toxoids and Pertussis Vaccine Adsorved Product Information. Physicians Desk Reference 2049, 1982.

29. Fulginiti, V.: Immunization in Clinical Practice. J.B. Lipincott Company, 1982

30. Olshin, I.: Infectious disease vaccines: Primary care update and review. Modern Medicine Jan., 1982

31. Gonzales, E.: TV report on DTP galvanizes US pediatricians. JAMA 248:1: 12-23, 1982

32. Adler, S.: The effects and side effects of vaccines. Virginia Medical Journal 109:410-411, 1982

33. American Academy of Pediatrics: Report of the Committee on Infectious Diseases. Nineteenth Edition, 1982

34. Berg, J.M.: Neurological complications of pertussis immunization. Br Med J 2:24, 1958

35. Nelson, W.E.,Ed.: Texthook of Pediatrics. W.B. Saunders Company, 1959

2. **A family history of convulsions or neurologic disease.**

The following sources state a family history of convulsions or neurologic disease is a contraindication to any pertussis vaccination:

36. Kong, E.: Helv paediat Acta 8:90, 1953

2. Toomey, J.A., 1949

3. Cockburn, W.C., 1951

4. Sutherland, J.M., 1953

6. Medical Research Council, 1956

8. Merrill-National Laboratories, Inc., 1974

9. Vaccination Against Whooping Cough, 1974

10. Griffeth. A., 1978

11. Kulenkampff, M. et al, 1974

12. Immunization Against Whooping Cough, 1975

14. Valman, H.B., 1980

15. Lederle Laboratories Division, Inc., 1980

16. Robinson, R.J., 1981

Case histories and data presented in the following sources give additional evidence that children with a family histroy of convulsions or neurologic disease should not receive any pertussis vaccine:

19. Hopper, J., 1961

20. Hannik, C.A., 19/9

21. Stewart, G.T., 1979

3. A personal or family history of severe allergies.

The following sources indicate that a personal or family history of allergies is either a contraindication to pertussis vaccine or a cause for extreme caution or the administration of fractional doses. While Dr. Lawrence Steinman's study does not recommend any of these courses of action, it does suggest that a family history of allergies may play a role in genetic predisposition to severe reactions to the pertussis vaccine.

37. Editorial: J Pediat 43:746, 1953

38. Miller, H.G. and Stanton, J.B.: Neurological Sequelae of Prophylactic Innoculation. Quart J Med 23:1, 1954

39. Doval, J.H.: Letters, Int. Corresp. Soc. Allergists Series 17:78, 1954

40. Friedman, H.T.: Letters, Int. Corresp. Soc. Allergists Series 17:73, 1954

41. Crump, J.: Letters, Int. Corresp. Soc. Allergists Series 17:75, 1954

42. Halpern, S.R. and Halpern, D.: Reactions from DPT immunization and its relationship to allergic children. J Pediat 47:60-66, 1955

43. Hilton, M.L. and Burland, W.L.: Pertussis-containing vaccines: The relationship between laboratory toxicity tests and reactions in children. Symp Series Immunobiol Standard 13:150-156, 1970

44. Steinman, L. et al.: Murine model for pertussis vaccine encephalopathy: linkage to H-2. Nature 299: 738-740, 1982

1. Brody, M., 1947

19. Hopper, J., 1961

20. Hannik, C.A., 1970

36. Kong, E., 1953

45. Panel of Review of Bacterial Vaccines and Bacterial Toxoids: Diptheria and Tetanus Toxoids and Pertussis Vaccine Adsorbed Manufactured by Dow Chemical Company. Final Report 289-292, 1979

4. Any present active illness (such as a cold, diarrhea, otitis media, upper respiratory infection, fever, etc.) or active illness within the past 30 days.

Case histories, data or suggestions made in the following sources indicate that children who are ill or have been ill in the recent past weeks are at higher risk of reacting severely to the pertussis vaccine.

46. Globus, J.H. and Kohn, J.L.: Encephalopathy following pertussis vaccine prophylaxis. JAMA 141:507, 1949

47. Miller, J.J.: Pediatrics 7:126, 1951

1. Brody, M., 1947

2. Toomey, J.A., 1949

3. Cockburn, W.C., 1951

4. Sutherland, J.M., 1953

6. Medical Research Council, 1956

11. Kulenkampff, M. et al, 1974

13. Griffeth. A., 1978

14. Valman, H.B., 1980

16. Robinson, R.J., 1981

19. Hopper, J., 1961

20. Hannik, C.A., 1970

34. Berg, J.M., 1958

Senator HAWKINS. The hearing is concluded.
[Whereupon, at 12:07 p.m., the hearing adjourned.]

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